IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LAKEWOOD HEALTH SYSTEM AND NORTHWEST MEDICAL CENTER, *for themselves and on behalf of all other similarly situated class members,*	Civil Action No. 07-69 (GMS)
Plaintiffs,	JURY TRIAL DEMANDED
v.	CLASS ACTION
TRIWEST HEALTHCARE ALLIANCE CORP.,	
Defendant.	

MEMORANDUM OF LAW OF PLAINTIFFS
IN RESPONSE TO THE STATEMENT OF INTEREST OF THE UNITED STATES

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Dated: October 12, 2007

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

INTRODUCTION

Plaintiffs Lakewood Health System and Northwest Medical Centered filed their class action Complaint (D.I. 1) against Defendant TriWest Healthcare Alliance Corp. alleging, among other things, that Defendant's uniform refusal to reimburse Plaintiffs and similarly situated health care providers for services rendered by them to TRICARE beneficiaries enrolled in Defendant's privately-run TRICARE health benefits program breached an implied contract with Plaintiffs and unjustly enriched Defendant. Defendant filed a Motion to Dismiss the Complaint (D.I. 11-12, 16) arguing, among other things, that (1) the United States alone is liable for Plaintiffs' claims; (2) jurisdiction of this matter is properly with TRICARE Management Activity ("TMA"); and (3) Plaintiffs failed to state claims. The United States filed a Statement of Interest ("SOI") (D.I. 22) to provide its position on certain aspects of the Complaint and the Motion to Dismiss.

NATURE AND STAGE OF PROCEEDINGS

1.0 Most prominently, the United States has wholly rejected Defendant's arguments that the Complaint should be dismissed based on the claim that the United States is the real party in interest or a necessary or indispensable party. Consistent with Plaintiffs' opposition to the Motion to Dismiss, the United States has made clear that (1) Defendant, and *not* the United States, would be solely liable for any judgment awarded to Plaintiffs, (2) Defendant could fully satisfy any such judgment, (3) government funds would not be subject to any such judgment, and (4) the United States "*does not want to be a party.*" *See* SOI at 12.

2.0 The United States has confirmed that Plaintiffs were not required to exhaust any administrative remedies.

2.1 Plaintiffs' claims amount to a dispute regarding a requirement of the law or regulation. Therefore, Plaintiffs' claims are, by definition, non-appealable and, thus, could not have been appealed under the TRICARE administrative review process.

2.2 The United States' own framing of the issue as being whether "plaintiffs' incurred charges fall within the definition of facility charges and whether Plaintiffs properly claimed those charges," *see* SOI at 16, actually demonstrates, as argued in Plaintiffs' Opposition to Defendant's Motion to Dismiss ("Plaintiffs' Opposition") (D.I. 15), that the issue of what reimbursement is required under 32 C.F.R. § 199.14(a)(5) is "non-appealable" and, therefore, could not have been appealed through any administrative review process.

2.3 By suggesting only that the underlying "Subject Claims" of Plaintiffs *could* have been appealed through the TRICARE administrative review process, the United States has necessarily conceded that such an administrative review is not mandatory and, as discussed herein and in Plaintiffs' previous papers, "exhaustion" should not be required by the Court.

3.0 Although presently premature, a review of the underlying merits of Plaintiffs' claims demonstrates that Plaintiffs have, in fact, billed for the facility charges associated with the Subject Claims utilizing the only means available to Plaintiffs for so billing, a point the SOI fails to acknowledge.

ARGUMENT

I. THE UNITED STATES HAS REJECTED DEFENDANT'S ARGUMENTS THAT THE UNITED STATES IS THE REAL PARTY IN INTEREST OR A NECESSARY OR INDISPENSABLE PARTY

Recognizing that the "Complaint does not challenge any TRICARE regulations or present any claim against the United States," the SOI squarely rejects Defendant's arguments that the United States is the real party in interest or a necessary or indispensable party in this

matter. *See* SOI at 4 ("The fact that TRICARE is a federally-funded program, authorized by federal statute, does not make the United States the real party in interest because the nature of the program and source of funding does not create a contractual relationship between the government and plaintiffs.") *Id.*

On the strength of *Board of Trustees of Bay Med. Ctr. v. Humana Military*, 447 F.3d 1370, 1374 (Fed. Cir. 2006) ("*Bay Medical*"), the case principally relied upon by Plaintiffs in arguing that the United States is not the real party in interest, the United States confirmed that it is not the real party in interest because, as Plaintiffs themselves have noted, "[s]hould the Court award plaintiffs money damages in this case, defendant alone would be liable for the judgment." *See* SOI at 8.

Indeed, according to the United States, the fact that Defendant will be held solely liable refutes Defendant's argument that the United States is a necessary party. Like Plaintiffs, the United States has explained that "defendant's claim that the United States is a necessary party is based on the erroneous premise that if plaintiffs prevail the judgment will be paid by the United States." *See* SOI at 11. To the contrary, as the SOI notes, "if plaintiffs prevail on the claims they have brought, i.e., implied contract and unjust enrichment claims against defendant, then they can receive full recovery from defendant." *Id.*[1]

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[1] The United States also explained that it could not be considered indispensable under the four factors for indispensability under *Gardiner v. Virgin Islands*, 145 F.3d. 635 (3d. Cir. 1998), noting that there would be no prejudice to the United States or the parties because the United States would not be bound by a judgment against Defendant and the parties would have the opportunity to present their cases in full, and also noting that a judgment would be limited to Plaintiffs' contract claims, which judgment could be recovered fully from Defendant. *See* SOI at 12-13.

In rejecting Defendant's arguments that the United States is the real party in interest or a necessary or indispensable party, the United States necessarily rejected the following assertions of Defendant:

- "[B]ecause TriWest is processing TRICARE claims from the non-network hospitals on the government's behalf, the Court cannot grant relief without affecting the federal treasury and interfering with TMA's administration of its TRICARE program," *see* TriWest Opn. Br. p. 21;

- "Because the government is the real party in interest, TriWest is immune from suit to the same extent the United States is immune," *see* TriWest Opn. Br. p. 21;

- "In this case, the government is the necessary party because, absent the government's participation, the Court cannot grant 'complete relief,'" *see* TriWest Opn. Br. p. 23;

- "The government is also a necessary party because any judgment by the Court would, 'as a practical matter,' impair or impede the government's ability to protect its regulatory interests," *see* TriWest Opn. Br. p. 23;

- "[L]itigating this suit without the government would subject TriWest to a substantial risk of multiple, 'inconsistent obligations,'" *see* TriWest Opn. Br. p. 24;

- "[L]itigation would prejudice and unduly interfere with TMA's interests and obligations to administer a uniform TRICARE program," *see* TriWest Opn. Br. p. 25;

- "Although TriWest may be 'at-risk' if it promised to pay claims at amounts in excess of the federally mandated allowable charge, it does not follow that TriWest is 'at-risk' for amounts needed to correct underpayments," *see* TriWest Rep. Br. pp. 11-12; and

- "Without TMA's involvement, the Court cannot know its official position regarding its own regulation and any decision will necessarily infringe on TMA's control over federal program benefits," *see* TriWest Rep. Br. p. 12.

The United States' position that it is *not* the real party in interest and *not* a necessary or indispensable party (indeed, the United States has expressly stated that "it does not want to be

party"), demonstrates the strength of Plaintiffs' arguments on these issues, and weighs heavily against a dismissal of the Complaint on these grounds.[2]

II. THE UNITED STATES HAS CONFIRMED THAT PLAINTIFFS WERE NOT *REQUIRED* TO PARTICIPATE IN ANY ADMINISTRATIVE REVIEW PROCESS.

A. The Very Nature Of The Subject Claims Makes Them Non-Appealable.

The United States agrees with Plaintiffs that the "claims plaintiffs have pled against defendant could not be heard as part of the TRICARE appeal process because they are contract issues between private parties." *See* SOI at 15. Nevertheless, the United States contends that the issue whether Plaintiffs' individual '"Subject Claims' would be paid 'as billed' under TRICARE's regulations and policies" is an issue that "*could*" have been raised through the TRICARE administrative appeal process. *Id.* However, the United States has not accurately characterized the dispute regarding each such Subject Claim.

Reduced to its simplest terms, the dispute surrounding each Subject Claim involves Plaintiffs' belief, on the one hand, that 32 C.F.R. § 199.14(a)(5)(xi) ***requires*** Defendant to reimburse, "as billed," non-network participating hospitals for facility ***charges*** incurred when rendering certain outpatient services[3] provided to TRICARE beneficiaries, and Defendant's belief, on the other hand, that it is ***required*** by the regulation to pay *only* the "CHAMPUS-

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[2] The failure of the United States to address Defendant's arguments on preemption and lack of standing cannot be ignored. If the United States believed that Plaintiffs' claims were in fact preempted, there can be little doubt that the United States would have brought this to the Court's attention. The failure of the United States to do so can only lead to the conclusion that Defendant's arguments on this issue shares the same fate as Defendant's arguments on real party in interest and necessary or indispensable party. The same can obviously also be said about Defendant's argument regarding primary jurisdiction.

[3] As will be developed more fully during discovery, the Subject Claims involve outpatient services falling within 32 C.F.R. § 199(a)(5)(i)-(ix) and (xi).

allowable charge" that corresponds to these services *but not* the facility ***charge*** associated with such services.

Properly characterized, the dispute surrounding each Subject Claim is not one that could have been appealed under the TRICARE administrative review process because any such dispute necessarily raises a question about "a requirement of the law or regulation," namely, what reimbursement is ***required*** under § 199.14(a)(5). Indeed, a closer reading of the SOI demonstrates that even the United States is hard-pressed to define the dispute as something other than a non-appealable "dispute regarding a requirement of the law or regulation." Thus, the SOI frames the issue as whether "plaintiffs' incurred charges fall within the definition of facility charges and whether plaintiffs properly claimed those charges." *See* SOI at 16.

Significantly, in all events, there is no dispute that the "facility charges" claimed by Plaintiffs are to be paid "as billed." *See* SOI at 16 (stating "there is no dispute that 'facility charges' are paid as billed"). Nor can there be any real dispute that such "facility charges" are charges that are different from and, in fact, "in addition to," charges that are reimbursed at CMAC. *See* SOI at 21 ("TRICARE can pay a facility charge, in addition, but that facility charge is not the difference between the billed amount for a service covered by a CMAC and the CMAC, but a *separate charge* to cover the use of the facilities, which is to compensate the hospital for its overhead, non-professional staff, depreciation, etc.") (emphasis added). However, there is a dispute as to whether Defendant is, in fact, required to pay the "facility charges" claimed by Plaintiffs, but that dispute is not a question to be decided now, on Defendant's Motion to Dismiss.

B. By Conceding That Plaintiffs Are Not *Required* To Exhaust Their Administrative Remedies, The United States Has Refuted Defendant's Argument That Plaintiffs' Alleged Failure To Exhaust Such Administrative Remedies Is A Grounds For Dismissal

Even accepting the United States' assertion that Plaintiffs' underlying Subject Claims *could* constitute an "appealable issue,"[4] Plaintiffs submit that it would be an abuse of this Court's discretion to require Plaintiffs to submit a multitude of Subject Claims for administrative review.

1. Exhaustion Is Not Required Under CHAMPUS

By using the word "could" as opposed to "must" in connection with Plaintiffs' potential invocation of the CHAMPUS administrative appeals process, *see* SOI at 15, the United States has conceded, as it must, that "*the CHAMPUS enabling statutes and regulations do not prescribe administrative appeals, see* 10 U.S.C. §1079; 32 C.F.R. §199.10." *I.M. Hofmann v Hammack, et al.*, 82 F. Supp. 2d 898, 900 (N.D. Ill. 2000) (emphasis added). Consequently, nothing in the

[4] The deference "analysis" in the SOI puts the cart before the horse. *See* SOI at 18 n.6. Although administrative agencies, like TMA here, regularly cite "deference" as a backstop to support their positions, Article III of the Constitution acts as the necessary check on agency disregard for the will of Congress. Under the *Chevron* test governing the Court's review, the first question is "whether Congress has directly spoken to the precise question at issue." *Chevron U.S.A. Inc. v. National Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984). "If the intent of Congress is clear, that is the end of the matter, for the court, as well as the agency must give effect to the unambiguously expressed intent of Congress." *Id.* at 843. Only if the statute is "silent or ambiguous with respect to the specific issue" does the Court proceed to inquire into "whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. The Court does not make this inquiry, however, "if Congress has spoken." *Granutec, Inc. v. Shalala*, 1398 U.S. App. LEXIS 6685, *20 (4th Cir. April 3, 1998) (Exhibit A). In this case, not only has Congress spoken to the issue, the United States' request for deference ignores that there are instances in which courts have interpreted TRICARE regulations on their own, without seeking the guidance of TMA. *See Baptist Phys. Hosp. Org., Inc. v. Humana Military Healthcare Servs., Inc.*, 2007 U.S. App. LEXIS 6447, at *14 (6th Cir. Mar. 21, 2007) (Exhibit B) (utilizing de novo standard of review to interpret TRICARE regulations dealing with "capital payments"); *Bd. of Trs. of Bay Med. Ctr., et al. v. Humana Military Servs.*, 2004 U.S. Dist. LEXIS 22147, at *15 (N.D. Fla. Mar. 16, 2004) (Exhibit C) (resolving issue that turned on question of regulatory interpretation without referring case to TMA).

SOI alters the view that Plaintiffs were not required to exhaust the CHAMPUS administrative remedies. Indeed, where, as here, there is no express requirement for exhaustion, "sound judicial discretion governs." *Id.* (citing *McCarthy v. Madigan*, 503 U.S. 140, 144 (1991)); *see also Holton v. Blue Cross Blue Shield of South Carolina*, 56 F. Supp. 2d 1347, 1353 (M.D. Ala. 1999) ("When Congress has not prescribed exhaustion, whether to require exhaustion is a matter within the Court's discretion."). Accordingly, "[this Court] need not require administrative exhaustion [where as here] the statute is silent." *Hoffmann*, 82 F. Supp. at 900.

2. The Court's Discretion Should Not Be Exercised In Favor of Requiring Exhaustion

"Two factors guide the court's decision in how to exercise its discretion regarding exhaustion in a particular case. First, whether requiring exhaustion would further the policies underlying the exhaustion doctrine; and, second, whether an exception to the doctrine applies." *See Holton*, 56 F. Supp. 2d at 1354.

a. The Policies Underlying The Exhaustion Doctrine Do Not Support Requiring Exhaustion Here

The policies underlying the exhaustion doctrine have been described in several ways, none of which would be furthered by requiring exhaustion here. Among these policies are (1) "[a]dministrative remedies exist so an aggrieved person can first seek relief within the agency before involving the courts" [and] so that the "agency gets the first crack at reconsidering the claim," *Hofmann*, 82. F. Supp. 2d at 900; (2) "judicial economy by preventing piecemeal judicial review of agency action and facilitates judicial review by allowing the administrative tribunal to use its expertise to develop a complete factual record," *Trauma Service Group v. Keating, at al.*, 907 F. Supp. 110, 113 (E.D. Pa. 1995); and (3) avoidance of "premature interruption of the administrative process; ... [lets] the agency develop the necessary factual background;

...[permits] the agency to exercise its discretion or apply its expertise ...; [and gives] the agency a chance to discover and correct its own errors," *Holton*, 56 F. Supp. 2d at 1354.

On the facts here, none of these policies is furthered by the application of the exhaustion doctrine. Here, Plaintiffs have previously raised their dispute with Defendant in countless discussions and correspondence, giving Defendant ample opportunity to resolve this matter over the last three years. *See* Complaint ¶ 38. Moreover, piecemeal judicial review would not be prevented on these facts because the case concerns the Defendant's uniform refusal to reimburse Plaintiffs for the facility charges incurred and billed, with respect to the Subject Claims. Furthermore, to the extent Defendant has not developed a *complete* factual record of the issue during the last three years that the dispute has been pending, the discovery process attendant to this litigation will fill in any gaps. Accordingly, none of these policy considerations weigh in favor of requiring Plaintiffs to exhaust administrative remedies by resubmitting to TMA each of a multitude of claims where: (1) the dispute has been ongoing for three years; (2) there are no additional facts Defendant needs to make its determination; and (3) Defendant has unequivocally stated that its position, albeit incorrect, is that it paid Plaintiffs what was required under the regulations.

b. Other Facts Weigh Against Requiring Exhaustion Here

Even if the policies underlying the exhaustion doctrine would be furthered in a particular case, a court will not require exhaustion in instances where, as is the case here, (1) exhaustion is futile; (2) the claim will clearly be denied or administrative action will not resolve the merits of the claim; (3) the administrative remedy is inadequate because it does not exist, or would unreasonably delay the action; or (4) the challenged agency action involves a clear and unambiguous violation of statutory rights or constitution rights. *See Trauma Service Group*, 907 F. Supp. at 113; *Holton*, 56 F. Supp. 2d at 1354.

Here, it is clear that resubmission of the Subject Claims and exhaustion of the appeal process would be futile, as Defendant would simply reiterate its position that no further payment is required under the regulation on the Subject Claims. *See* TriWest Op. Br. 2. Further, exhaustion would unnecessarily delay the action because it would require Plaintiffs to appeal thousands of claims, all of which were paid in accordance with the same improper "policy," which is at the center of this dispute. Moreover, as alleged in the Complaint, Defendant's failure to pay in accordance with the regulations violates the Plaintiffs' statutory right to appropriate payments and exhaustion is not required.

3. The Allegations Of The Complaint Are Sufficient To Survive A Motion To Dismiss

At this stage of the proceedings, Plaintiffs' allegations that they have "*duly* billed their claims for outpatient services in the manner required by the applicable regulations," *see* Complaint ¶ 32, are sufficient to state a claim. Further, in this case, Plaintiffs have done better. Plaintiffs alleged not only that the issues were non-appealable in the first place, but that, in all events, exhausting their administrative remedies would have been futile. As Plaintiffs specifically alleged in their Complaint:

- TriWest's failure to pay the Facility Charges for the Subject Claims, despite (i) the regulations governing TRICARE, (ii) TMA's longstanding policy, and (iii) the DoD's letter of April 14, 2006 directly addressing this issue, is not appealable under the regulations governing TRICARE.

- Nevertheless, Plaintiffs and their counsel have attempted, unsuccessfully, through numerous discussions and correspondence with TriWest, to cause TriWest to pay the Facility Charges for the Subject Claims. Throughout this dialogue, TriWest has been steadfast in its unwillingness to make such payment. Accordingly, the claims of the Plaintiffs and the Class members alleged herein are ripe for adjudication, as further efforts by Plaintiffs or any Class member to resolve this dispute without litigation would be futile.

See Complaint at ¶¶ 37, 38. Having duly pled the non-appealability of the issues presented and the futility of their previous efforts to engage the Defendant, nothing more is required of Plaintiffs. The Court should permit the case to go forward on the merits.

III. ALTHOUGH PRESENTLY PREMATURE, ANY CONSIDERATION OF THE UNDERLYING MERITS DEMONSTRATES THAT THE SOI FAILS TO ADDRESS THE FACT THAT THE ONLY MEANS TO "BILL" FOR FACILITY CHARGES ASSOCIATED WITH THE SUBJECT CLAIMS IS THE PRECISE METHOD THAT PLAINTIFFS EMPLOYED[5]

The United States has confirmed Plaintiffs' position that, with respect to the Subject Claims, (1) a fee for "facilities charges" is payable to Plaintiffs, as dictated by 32 C.F.R. § 199.14(a)(5)(xi), and (2) ***this fee is in addition to any payments*** that are made under 32 C.F.R. § 199.14(a)(5)(i)-(x) (*i.e.*, CMAC payments).[6] According to the United States:

> Under DoD regulations, when there is a CMAC, that is the maximum amount TRICARE can pay for that *claimed service*; no other charges for the *same service* are payable by TRICARE. TRICARE can pay a facility charge, *in addition*, but that facility charge is not the difference between the billed amount for a service covered by a CMAC and the CMAC, but a *separate charge* to cover the use of the facilities, which is to compensate the hospital for its overhead, non-professional staff, depreciation, etc.

SOI at 21 (emphasis added) (citation omitted).

Notwithstanding that Plaintiffs and the United States are in agreement that facility charges may be paid separate and apart from the payment of CMAC, there is no means for

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5 Contrary to the United States' contention, Plaintiffs have not "misrepresented" the Department of Defense's position—in point of fact, this Section shows that not only was there no misrepresentation, but that in fact the United States and Plaintiffs *agree* that providers, such as Plaintiffs, are entitled to payment for facility charges or costs incurred in rendering hospital outpatient services to TRICARE beneficiaries *in addition* to CMAC rates for the actual outpatient services rendered. The only issue stems from the United States' misperception of the Subject Claims.

6 This conclusion is reached even assuming, arguendo, that the United States is entitled to deference in terms of its interpretation of the TRICARE regulations, a point that Plaintiffs strenuously dispute.

Plaintiffs to separately and distinctly bill solely for "facility charges" when submitting the Subject Claims. As the United States correctly noted, "[e]ach institutional billing . . . must be itemized fully and sufficiently descriptive for [TRICARE] to make a determination of benefits."[7] *See* SOI at 19-20. However, the UB-92 form, which the parties acknowledge to be the standard billing form,[8] requires all costs incurred in connection with the Subject Claims to be tied to a specific service (which service Defendant then contends must be reimbursed only at CMAC).

This is immediately apparent from a review of the UB-92, a sample of which has been attached hereto as Exhibit "D." In addition to reporting personal information that identifies the TRICARE beneficiary to whom a hospital outpatient service was provided, the UB-92 requires, among other things:

- in box 43, a description of the service provided;
- in box 42, the revenue code information[9] that corresponds to the service provided;
- in box 44, the HCPCS/CPT code information[10] that corresponds to the service provided; and

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7 32 C.F.R. § 199.6(b)(1)(ii)(A).

8 TRICARE Provider Handbook at 85, 124 ("the UB-04 form is used by hospitals . . . to bill government and commercial health plans"); *see also* TRICARE Claims and Billing Tips [(West)] http://www.tricare.mil/TRICARESmart/product.aspx?id=230&CID=92&RID=1 ("Network providers are required to file claims electronically. All others file electronically or on UB92...").

9 "Revenue codes" are used to identify specific accommodation and/or ancillary charges. *See* Centers for Medicare and Medicaid Services ("CMS") Medicare Claims Processing Manual, Pub. 100-04 at 70 http://www.cms.hhs.gov/Transmittals/downloads/R1104CP.pdf. All of the Subject Claims include claims for which no separate facility revenue code is applicable.

10 "HCPCS/CPT Code" stands for Healthcare Common Procedure Coding System and includes HCPCS codes developed by CMS that identify products, supplies, and services not included in the CPT codes. "CPT Codes" developed by the American Medical (Continued...)

- in box 47, the total charge (*i.e.*, ***"facility charges"***) associated with the service provided.[11]

In analyzing the UB-92, the total charge for the service billed represents the charge allocated by the facility for the given service. This amount (*i.e.*, the "billed charges") is established by a hospital determining how much it needs to charge for a given procedure to cover its building costs, staffing costs, drugs, supplies, and overhead costs allocated to the procedure in question. Hence, "billed charges," as referred to in box 47 of the UB-92, equates to "facility charges," as that term is defined in 32 C.F.R. § 199.2(b).

With the above explanation in mind, to suggest that, with respect to the Subject Claims, Plaintiffs separately bill, as a line item charge on a UB-92, solely for the "facility charges," without reference to the procedure or service rendered, suggests a billing approach that simply does not exist in the outpatient setting. Significantly, what is not disputed by either Defendant or the United States is that for the vast majority of outpatient services, and all of those constituting the Subject Claims, there is no mechanism by which to separately bill only for "facility charges," as these charges, or costs, are associated with specific procedures that are required to be listed in the respective UB-92 claims and reflected in box 47 of the UB-92.[12]

(Continued...)

Association that identify medical services and procedures furnished by physicians and other health care professionals. *See* www.cms.hhs.gov/MedHCPCSGenInfo/.

11 Hospitals use extensive charge masters in order to bill patients, the government and commercial health plans. Charge masters are computer files designed to include all of the chargeable items in the hospital, and to designate the costs associated with each inpatient and outpatient service. When generating a UB-92, the charges and costs associated with a reported outpatient service are pulled from the charge master and included in the UB-92.

12 *See* Exh. A.

Moreover, the amount that is required to be paid a given hospital for the "facility charges" it incurs in rendering a given service or procedure is determined, not by the government or regional contractors, but by the provider itself. As the United States confirmed in the SOI, "'facility charges' are to be paid as billed." *See* SOI at 16; *see also* 32 C.F.R. § 199.14(a)(5)(xi)."[13] In mandating that "facility charges" be paid "as billed," the regulations clearly recognize that the costs associated with providing a given service vary from facility to facility. Despite the United States' apparent desire to now rewrite the regulations to require payment for only, in its words, some non-defined, amorphous "true facility charges," neither the United States nor Defendant can escape the fact that "'facility charges' are to be paid as billed." *See* SOI at 16. Defendant's continued insistence that such charges are not payable presents a non-appealable issue that may be vindicated only by Plaintiffs' implied contract and unjust enrichment claims.[14]

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13 *See* SOI at 19.

14 *See* Complaint ¶ 37; SOI at 19.

CONCLUSION

For all of the foregoing reasons, Plaintiffs respectfully renew their request that the Court deny in its entirety Defendant's Motion to Dismiss.

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Dated: October 12, 2007

EXHIBIT "A"

1 of 2 DOCUMENTS

GRANUTEC, INCORPORATED, Plaintiff-Appellee, v. DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES; MICHAEL FRIEDMAN, M.D.; FOOD & DRUG ADMINISTRATION, Defendants, and GENPHARM, INCORPORATED, Intervenor-Appellant. BOEHRINGER INGELHEIM CORPORATION, Amicus Curiae. GRANUTEC, INCORPORATED, Plaintiff-Appellee, v. DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES; MICHAEL FRIEDMAN, M.D.; FOOD & DRUG ADMINISTRATION, Defendants-Appellees, and GENEVA PHARMACEUTICALS, INCORPORATED, Intervenor-Appellant. BOEHRINGER INGELHEIM CORPORATION, Amicus Curiae.

No. 97-1873, No. 97-1874

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

1998 U.S. App. LEXIS 6685; *46 U.S.P.Q.2D (BNA) 1398*

October 1, 1997, Argued
April 3, 1998, Decided

NOTICE: [*1] RULES OF THE FOURTH CIRCUIT COURT OF APPEALS MAY LIMIT CITATION TO UNPUBLISHED OPINIONS. PLEASE REFER TO THE RULES OF THE UNITED STATES COURT OF APPEALS FOR THIS CIRCUIT.

SUBSEQUENT HISTORY: As Amended May 7, 1998.

Reported in Table Case Format at: *1998 U.S. App. LEXIS 10984*.

PRIOR HISTORY: Appeals from the United States District Court for the Eastern District of North Carolina, at Raleigh. Terrence W. Boyle, Chief District Judge. (CA-97-485-5-BO).

DISPOSITION: REVERSED.

LexisNexis(R) Headnotes

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[HN1] Under the Food, Drug, and Cosmetic Act generally, pioneer drug manufacturers must obtain Food and Drug Administration approval for any new drug by filing a New Drug Application, which requires the submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act
Patent Law > Claims & Specifications > Enablement Requirement > General Overview
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview

[HN2] One primary innovation of the Hatch-Waxman Amendments of the Food, Drug, and Cosmetic Act, specifically *21 U.S.C.S. § 355*, allows companies subsequently seeking to produce and market a generic form of a pioneer drug to avoid filing a full New Drug Application (NDA). Instead, these companies may file only an Abbreviated New Drug Application (ANDA), in which they may rely on the findings of safety and effectiveness included in the original NDA. The only important new information that must be included in the ANDA regards the generic company's position vis-a-vis the original patent, and the company must make one of four certifications: I) that no patent for the pioneer drug has been filed; II) that the patent for the pioneer drug has expired; III) that the patent for the pioneer drug will expire on a particular date; or IV) that the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic. *21 U.S.C.S. § 355(j)(2)(A)(vii)*. The last of these is commonly referred to as a "Paragraph IV" certification.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

Patent Law > Infringement Actions > Defenses > Experimental Use & Testing
Patent Law > U.S. Patent & Trademark Office Proceedings > Continuation Applications > General Overview
[HN3] If a generic company chooses Paragraph IV certification under the Hatch-Waxman *Amendments, 21* U.S.C.S. *§ 355*, of the Food, Drug, and Cosmetic Act, it must notify both the patent owner and the New Drug Application holder of the Abbreviated New Drug Application (ANDA). That notification must include the basis for why the proposed generic does not infringe upon the patent, or why that patent is invalid. *21 U.S.C.A. § 355(j)(2)(B)*. After such notice, an action for patent infringement must be brought within 45 days, and if no such action is brought, the Food and Drug Administration (FDA) may approve the ANDA. If an infringement action is brought, FDA cannot approve the ANDA for 30 months, unless the matter is adjudicated in the ANDA applicant's favor or the court hearing the suit orders a shorter or longer waiting period. *21 U.S.C.S. § 355(j)(4)(B)(iii)*.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act
[HN4] See *21 U.S.C.S. § 355(j)(4)(B)(iv)*.

Administrative Law > Agency Rulemaking > Informal Rulemaking
Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act
[HN5] See *21 C.F.R. § 314.107(c)(1)*.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act
Governments > Legislation > Interpretation
[HN6] The language of *21 U.S.C.S. § 355(j)(4)(B)(iv)* is plain and unambiguous. It does not include a successful defense requirement, and indeed it does not even require the institution of patent litigation. In light of this plain and unambiguous language, the Food and Drug Administration's interpretive authority with regard to the statutory provision is limited to the extent that Congress has already spoken directly to the issue addressed by the regulation.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act
Governments > Legislation > Statutes of Limitations > Time Limitations
Patent Law > Infringement Actions > Defenses > Experimental Use & Testing
[HN7] All that Congress requires for the 180-day exclusivity period under the Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act, specifically *21 U.S.C.S. § 355*, is: (1) the filing of the first Abbreviated New Drug Application that includes a Paragraph IV certification; and (2) either (a) the first commercial marketing of the drug (after no infringement suit has been filed within 45 days or no resolution to such a suit has been reached after the expiration of the 3-month stay), or (b) a decision that the patent in question is either invalid or not infringed. *21 U.S.C.S. § 355(j)(4)(B)(iv)*.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act
[HN8] The "successful defense" requirement of C.F.R. *§ 314.107(c)(1)* adds a requirement not contemplated in the statute, and renders superfluous *21 U.S.C.S. § 355(j)(4)(B)(iv)(I)*, which allows the 180-day period to begin at the time Food and Drug Administration receives notice of marketing of the drug, regardless of the outcome of any infringement suit.

Administrative Law > Separation of Powers > Legislative Controls > General Overview
Constitutional Law > The Judiciary > Case or Controversy > Constitutionality of Legislation > General Overview
Governments > Legislation > Interpretation
[HN9] The determination of a regulation's validity under its enabling statute involves a two-stage process. Analysis of legislative history and policy goals occurs at the second stage, and is reached only if Congress, through the relevant statute, has not spoken directly to the issue in question. If Congress has so spoken, that is the end of the matter; a court simply does not undertake to assess the reasonableness of the agency's interpretation of the statute if Congress has spoken.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act
Governments > Legislation > Interpretation
[HN10] Having found the exclusivity requirements embodied in the statutory language of *21 U.S.C.S. § 355(j)(4)(B)(iv)* clear and conclusive, the court is bound to hold invalid any attempt to alter the terms of that statute.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[HN11] The "successful defense" requirement in *21 C.F.R. § 314.107(c)(1)* amounts to an alteration because it adds a requirement to *21 U.S.C.S. § 355(j)(4)(B)(iv)* that Congress never contemplated. Further, the idea that any 180-day exclusivity period must be premised on the successful defense of an infringement suit results in the evisceration of *21 U.S.C.S. § 355(j)(4)(B)(iv)(I)*, which clearly contemplates an exclusivity period beginning -- whether or not an infringement suit has come to resolution -- on the date of first commercial marketing by the first Abbreviated New Drug Application filer. Thus, the "successful defense" requirement contained in *21 C.F.R. § 314.107(c)(1)* is an invalid addition to the statutory requirements for exclusivity.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[HN12] For purposes of the exclusivity under *21 U.S.C.S. § 355(j)(4)(B)(iv)*, the certification relates back to the date of the Abbreviated New Drug Application. This interpretation does not clearly conflict with either the regulations or the statute.

Administrative Law > Agency Rulemaking > Rule Application & Interpretation > General Overview
Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act
Patent Law > Infringement Actions > Defenses > Experimental Use & Testing

[HN13] For purposes of establishing the effective date of approval, *21 C.F.R. § 314.107(e)* defines "a decision of a court" in terms of a final judgment from which no appeal can be or has been taken. *Section 314.107(e)* goes on to state that "the date of final decision" shall be, in the case of no appeal by the patent holder, the date on which the right to appeal lapses, and, in the case of an appeal, the date of the first decision or order by a higher court affirming the district court's non-infringement decision. *21 C.F.R. § 314.107(e) (1997).*

Administrative Law > Agency Rulemaking > Rule Application & Interpretation > General Overview
Administrative Law > Judicial Review > Standards of Review > Statutory Interpretation

[HN14] The Food and Drug Administration's interpretation of the statutory language and its own regulations is a permissible, reasonable interpretation of a complicated legislative framework that reflects a considered balance of competing statutory goals.

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JUDGES: Before RUSSELL * and MOTZ, Circuit Judges, and PHILLIPS, Senior Circuit Judge.

* Judge Russell heard oral argument in this case but died prior to the time the opinion was filed. The opinion is filed by a quorum of the panel. 28 U.S.C.A. § 46(d) (West 1993).

OPINION

OPINION

PER CURIAM:

This appeal concerns the Food **[*3]** and Drug Administration's enforcement of certain provisions of *21 U.S.C.A. § 355*, part of the 1984 revision to the Food, Drug, and Cosmetic Act known collectively as the "Hatch-Waxman Amendments." *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984). The district court determined that the Food and Drug Administration (FDA) incorrectly declined to apply the terms of a regulation, promulgated pursuant to the Hatch-Waxman Amendments, that the District Court for the District of Columbia had all but held invalid in *Mova Pharmaceutical Corp. v. Shalala, 955 F. Supp. 128 (D.D.C. 1997)*.

At the time of the district court's decision in the present case, FDA had decided:

> to acquiesce temporarily -- pending an appellate decision overturning the district court decision or a favorable ruling on summary judgement -- in the *Mova* preliminary injunction in order to promote administrative uniformity and to avoid forum shopping problems that would lead . . . applicants back to the United States District Court for the District of Columbia where the *Mova* decision was rendered.

Brief of FDA at 11. Genpharm, Inc., and **[*4]** Geneva Pharmaceuticals, Inc., intervened in opposition to Granutec's motion for an injunction, with each cross-claiming that it was entitled to the 180-day exclusive marketing period Granutec sought to enjoin.

For the reasons set forth within, we conclude that the regulation Granutec seeks to enforce is invalid. Further, we hold that, as the first applicant under the statute, Genpharm was entitled to a 180-day exclusivity period measured from March 3, 1997, until August 29, 1997. We therefore reverse the judgment of the district court.

I.

A.

The provision of the Hatch-Waxman Amendments relevant to this appeal concerns the availability of a 180-day market exclusivity period to the first company that seeks, under certain circumstances, to market a generic form of a patented drug approved by the FDA. [HN1] Under the Food, Drug, and Cosmetic Act generally, pioneer drug manufacturers must obtain FDA approval for any new drug by filing a New Drug Application (NDA), which requires the submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. All drug patent information is published by the FDA.

[HN2] One of the primary innovations **[*5]** of the Hatch-Waxman Amendments is an additional provision that allows companies subsequently seeking to produce and market a generic form of a pioneer drug to avoid filing a full NDA. Instead, these companies may file only an Abbreviated New Drug Application (ANDA), in which they may rely on the findings of safety and effectiveness included in the original NDA. The only important new information that must be included in the ANDA regards the generic company's position *vis-a-vis* the original patent, and the company must make one of four certifications: I) that no patent for the pioneer drug has been filed; II) that the patent for the pioneer drug has expired; III) that the patent for the pioneer drug will expire on a particular date; or IV) that the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic. *See 21 U.S.C.A. § 355(j)(2)(A)(vii) (West Supp. 1997)*. The last of these, commonly referred to as a "Paragraph IV" certification, is the certification at issue in this appeal.

[HN3] If a generic company chooses Paragraph IV certification, it must notify both the patent owner and the NDA holder of the ANDA application. That notification must include **[*6]** the basis for why the proposed generic does not infringe upon the patent, or why that patent is invalid. *See 21 U.S.C.A. § 355(j)(2)(B) (West Supp. 1997)*. After such notice, an action for patent infringement must be brought within 45 days, and if no such action is brought, FDA may approve the ANDA. If an infringement action is brought, FDA cannot approve the ANDA for 30 months, unless the matter is adjudicated in the ANDA applicant's favor or the court hearing the suit orders a shorter or longer waiting period. *See 21 U.S.C.A. § 355(j)(4)(B)(iii) (West Supp. 1997)*.

In addition, and here we reach the statutory provision contested in this appeal, the Hatch-Waxman Amendments also provide an incentive for companies to challenge patents and develop alternative forms of patented drugs by offering a 180-day period of market exclusivity to those who successfully make their Paragraph IV certifications. [HN4] The relevant provision states:

> (iv) If the application [ANDA] contains a certification described in [Paragraph IV] . . . and is for a drug for which a previous application has been submitted under this subsection continuing [sic: usually read as "containing"] such a certification, **[*7]** the application shall be made effective not earlier than one hundred and eighty days after--

> (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
>
> (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,
>
> whichever is earlier.

21 U.S.C.A. § 355(j)(4)(B)(iv) (West Supp. 1997). Thus, the statute grants a 180-day period of exclusive marketing rights to the first generic manufacturer to file an ANDA containing a Paragraph IV certification, measuring from the date it decides to begin marketing after the 30-month stay has expired (presumably assuming the risk of liability for patent infringement) or from the date of a favorable patent infringement decision, whichever is earlier.

Further, pursuant to *21 U.S.C.A. § 371(a)*, FDA may promulgate regulations for the enforcement of the Food, Drug, and Cosmetic Act as a whole, and has done so with regard to the 180-day market exclusivity provision. *See 21 U.S.C.A. § 371(a) (West 1972)*. [HN5] That **[*8]** regulation, found at *21 C.F.R. § 314.107(c)(1)*, states that:

> (1) If an abbreviated new drug application contains a certification that a relevant patent is invalid, unenforceable, or will not be infringed and the application is for a generic copy of the same listed drug for which one or more substantially complete abbreviated new drug applications were previously submitted containing a certification that the same patent was invalid, unenforceable, or would not be infringed and the applicant submitting the first application has successfully defended against a suit for patent infringement brought within 45 days of the patent owner's receipt of notice submitted under § 314.95, approval of the subsequent abbreviated new drug application will be made effective no sooner than 180 days from whichever of the following dates is earlier:
>
> (i) The date the applicant submitting the first application first commences commercial marketing of its drug product; or
>
> (ii) The date of a decision of the court holding the relevant patent invalid, unenforceable, or not infringed.

21 C.F.R. § 314.107(c)(1) (1997) (emphasis added). This provision, therefore, not only restates the statutory requirements **[*9]** for the 180-day exclusivity period, but additionally requires that "the applicant submitting the first application has successfully defended against a suit for patent infringement." *Id.*

B.

The regulation's addition to the requirements for the 180-day exclusivity period is commonly known as the "successful defense" requirement, and has been enforced since the regulation's adoption in 1994. Earlier, in 1989, an unwritten FDA interpretation of the statute requiring that the Paragraph IV applicant be sued in order to be eligible for the exclusivity period was challenged as unreasonable in *Inwood Laboratories, Inc. v. Young, 723 F. Supp. 1523 (D.D.C. 1989), appeal dismissed, 310 U.S. App. D.C. 61, 43 F.3d 712 (D.C. Cir. 1989)*. There, a district court granted a motion for a preliminary injunction against FDA on the ground that, because *21 U.S.C. § 355(j)(4)(B)(iv)* was clear on its face, a court should not "permit[] the FDA to read into [the statute] a requirement of a lawsuit which is simply not there." *723 F. Supp. at 1526*.

Nevertheless, FDA promlgated a regulation containing an even more demanding interpretation of the statute -- i.e., the "successful defense" requirement -- **[*10]** in 1994. That regulation was itself challenged in an injunction context last year in *Mova*, where the District Court for the District of Columbia, while not declaring the regulation invalid, stated that the likelihood was "very high" that a challenge to the "successful defense" portion of the regulation as an impermissible addition to the relevant statute would succeed. *Mova, 955 F. Supp. at 131*. In so doing, the district court declared:

> The language of the statute may be complex, and even cumbersome, but it is plain and unambiguous. It does not include a "successful defense" requirement, and indeed it does not even require the institution of patent litigation. It was Mova's first filing of an ANDA for micronized glyburide [the drug there in question] under paragraph IV, and not Upjohn's infringement suit, that required FDA to withhold approval from subsequent paragraph IV filers. . . . The operation of the statute on the facts of this case may appear to FDA to be unwise, and may ap-

> pear . . . to be an invitation for abuse, but their remedy lies with Congress, not this Court.

Id. at 130-31 (citing *Inwood, 723 F. Supp. at 1526*). Thus, *Mova* strongly **[*11]** implied that the regulation in question was not a permissible "interpretation" of the 180-day exclusivity provision in the statute.

C.

In the present case, Granutec successfully persuaded the district court to enjoin FDA from granting the 180-day marketing exclusivity period to its competitor, Genpharm, for the production of a generic form of Zantac, a medication for the treatment of ulcers and one of the largest-selling prescription drugs in the world. Granutec's argument in this regard was that, contrary to *Mova* , FDA erred in *not* applying the "successful defense" requirement. Granutec maintained that FDA's failure to follow its own regulation, which compelled the result that no ANDA applicant in this matter was entitled to 180-day exclusivity, was arbitrary and capricious. As stated above, FDA had adopted a position acquiescing in the *Mova* decision and its implications for the validity of the "successful defense" requirement. In granting the injunction, however, the district court cited the regulatory "successful defense" requirement, without further explanation.

Granutec's claim against Genpharm resulted from a series of efforts by various pharmaceutical companies **[*12]** to use the Paragraph IV certification to gain FDA approval for a generic form of Zantac. The original patents for the two operative forms of ranitidine hydrochloride (ranitidine), the active ingredient in Zantac, belonged to Glaxo-Wellcome, Inc. (Glaxo), the pioneer manufacturer of Zantac. The two forms of ranitidine, Forms 1 and 2, are considered equivalent by FDA, but are covered by different patents: *Patent No. 4,521,431 (the 431 patent)* covers Form 2 ranitidine, and will expire on June 4, 2002, and *Patent No. 4,128*, 658 (the 658 patent) covers Form 1, and expired on July 25, 1997. *See* Brief of FDA at 11, 34 & n.3.

The first company to challenge either patent was Genpharm, which, in February 1991, filed an ANDA for a generic ranitidine product, and included a Paragraph IV certification as to the *431 patent* for Form 2 ranitidine. Later, Genpharm amended that application to include a Paragraph IV certification as to the 658 patent as well. Glaxo filed an infringement suit within the 45-day statutory period, and prevailed in October 1995. *See Glaxo, Inc. v. Genpharm Pharmaceuticals, Inc.*, C.A. Nos. K-92-1831 and K-93-4228 (D. Md. Oct. 23, 1995). In 1996, Genpharm filed a Paragraph **[*13]** IV certification under its ANDA alleging non-infringement of the *431 patent* for Form 1 ranitidine, and again Glaxo sued. That case remained pending when this appeal was filed.

In January 1994, Geneva filed an ANDA for generic ranitidine, which included a Paragraph IV certification as to the *431 patent* for a Form 1 product. Glaxo sued Geneva, and that case also remained pending as of the time this appeal was filed.

In April 1994, Granutec filed an ANDA for generic ranitidine, which also included a Paragraph IV certification as to the *431 patent* for a Form 1 product. Glaxo sued, and Granutec prevailed in July 1996; Glaxo appealed that decision and lost on appeal when the Federal Circuit affirmed on April 4, 1997. *See Glaxo, Inc. v. Novopharm, Ltd., 931 F. Supp. 1280 (E.D.N.C. 1996), aff'd, 110 F.3d 1562 (Fed. Cir. 1997)*. In the wake of this decision, Glaxo and Granutec entered into a licensing agreement regarding the 658 patent, which provided that, in exchange for a substantial monetary payment, Glaxo would allow Granutec to begin marketing generic Zantac on July 10, 1997, fifteen days before the scheduled expiration of the 658 patent.

This case was instituted when Granutec, **[*14]** having entered into the 15-day licensing agreement with Glaxo for its generic version of Zantac, sought FDA approval of its ANDA effective July 10, 1997. FDA responded that it could not approve Granutec's ANDA effective as of July 10, 1997. Pursuant to its decision to acquiesce in *Mova* and that decision's implications for the "successful defense" requirement, FDA concluded that Genpharm was entitled to the 180-day marketing exclusivity period because Genpharm filed the first ANDA with a Paragraph IV certification for Zantac. FDA measured Genpharm's exclusivity period from March 3, 1997, the date that Glaxo's right to appeal expired in *Glaxo, Inc. v. Boehringer Ingelheim Corp., 954 F. Supp. 469 (D. Conn. 1996), judgment entered by 962 F. Supp. 295 (D. Conn. 1997), aff'd, 119 F.3d 14, 1997 WL 355339 (Fed. Cir. 1997)*, a wholly unrelated suit in which a district court determined that Boehringer Ingelheim's generic version of Form 1 ranitidine did not infringe upon Glaxo's *431 patent*.

This judgment, FDA claimed, satisfied the requirement of *21 U.S.C.A. § 355(j)(4)(B)(iv)* that, before the 180-day period of exclusivity can begin, there must be "*a* decision of **[*15]** *a* court in *an* action . . . holding the patent which is the subject of the certification to be invalid or not infringed." *21 U.S.C.A. § 355(j)(4)(B)(iv)(II)* (emphasis added). As FDA had decided to "acquiesce" in the *Mova* decision, it did not apply the additional "successful defense" requirement found in *21 C.F.R. § 314.107(c)(1)*.

On June 17, 1987, Granutec filed this action, seeking declaratory and injunctive relief against FDA, in the District Court for the Eastern District of North Carolina. Granutec alleged that no company was entitled to a 180-day exclusivity period and sought approval of its ANDA effective July 10, consistent with the terms of its license from Glaxo. Genpharm and Geneva intervened and cross-claimed, and, on July 3, 1997, the district court dismissed the two cross-claims and, *sua sponte*, granted a permanent injunction against FDA. This appeal followed. Although FDA was the party against whom the district court enforced the permanent injunction, on appeal the agency has realigned itself. FDA now asserts that the district court's injunction was proper and should be upheld.

On July 9, 1997, we entered a stay of the district court's injunction pending **[*16]** appeal. We also ordered Genpharm and Geneva each to post a five million dollar supersedeas bond to protect Granutec's stake in the event we ultimately affirmed the district court's order. Granutec thereafter executed an agreement with Genpharm wherein Genpharm waived any entitlement to exclusivity in favor of Granutec, but preserved Granutec's right to challenge Genpharm's claim to exclusivity. In the wake of this agreement, FDA approved Granutec's ANDA effective August 1, 1997, and Granutec has been marketing its generic version of Zantac since that date.

On August 6, 1997, the District Court for the District of New Jersey dismissed with prejudice Glaxo's infringement claim against Geneva. *See Glaxo, Inc. v. Geneva Pharmaceuticals, Inc., 1997 U.S. Dist. LEXIS 22132*, C.A. Nos. 94-1921 and 94-4589 (D.N.J. Aug. 6, 1997). FDA thereafter approved Geneva's ANDA as of August 29, 1997. On August 15, 1997, Genpharm prevailed over Glaxo in its infringement suit. *See GlaxoWellcome, Inc. v. Genpharm, Inc.*, No. 96-CIV-6719 (S.D.N.Y. Aug. 15, 1997). FDA approved Genpharm's ANDA effective August 22, 1997, and Genpharm has marketed its generic since that date.

II.

This case turns on a fundamental problem of administrative **[*17]** law: an agency's authority to interpret the statutes it is required to enforce.

A.

Genpharm and Geneva allege that the district court incorrectly required FDA to adhere to the "successful defense" requirement -- a requirement that both companies claim is invalid because it directly conflicts with the plain language of the statutory provision regarding the 180-day market exclusivity period. In support of this allegation, Genpharm and Geneva cite *Mova*, and other cases holding that regulations, like the one here, that add to rather than elucidate a statutory requirement go beyond an agency's authority to interpret legislative grants of power. We agree with their argument.

As Judge Robertson stated in *Mova* when he examined the validity of the "successful defense" requirement, [HN6] the language of *21 U.S.C.A. § 355(j)(4)(B)(iv)* is "plain and unambiguous. It does not include a 'successful defense' requirement, and indeed it does not even require the institution of patent litigation." *Mova , 955 F. Supp. at 130.* In light of this plain and unambiguous language, FDA's interpretive authority with regard to the statutory provision is limited to the extent that Congress has already **[*18]** spoken directly to the issue addressed by the regulation. *See Chevron U.S.A. v. Natural Resources Defense Council, 467 U.S. 837, 842-45, 81 L. Ed. 2d 694, 104 S. Ct. 2778 (1984).*

Here, that issue involves the exact requirements a generic manufacturer must satisfy to qualify for the 180-day market exclusivity period. By expressly including certain requirements in the statute to the exclusion of all others, Congress presumably intended that the statutory requirements would comprise the full measure of eligibility. As we held in *Cabell Huntington Hospital, Inc. v. Shalala, 101 F.3d 984, 990-91 (4th Cir. 1996)*, an agency cannot issue regulations that alter the statute's requirements for benefits the agency administers. [HN7] All that Congress required for the 180-day exclusivity period is: (1) the filing of the first ANDA that includes a Paragraph IV certification; and (2) either (a) the first commercial marketing of the drug (after no infringement suit has been filed within 45 days or no resolution to such a suit has been reached after the expiration of the 3-month stay), or (b) a decision that the patent in question is either invalid or not infringed. *See 21 U.S.C.A. § 355(j)(4)(B)(iv).*

[*19] Demanding a "successful defense" neither interprets the statute nor fills a gap left by statutory silence. Rather, [HN8] the "successful defense" requirement adds a requirement not contemplated in the statute, and, as Genpharm notes, renders superfluous *21 U.S.C.A. § 355(j)(4)(B)(iv)(I)*, which allows the 180-day period to begin at the time FDA receives notice of marketing of the drug, regardless of the outcome of any infringement suit. *See Foxglenn Investors L.P. v. Cisneros, 35 F.3d 947, 950-51 (4th Cir. 1994)* (declaring invalid a regulatory interpretation that rendered a section of the applicable statute superfluous).

Both Granutec and FDA argue that the regulation in question merely elucidates rather than adds to the requirements for the 180-day exclusivity period. Further, Granutec painstakingly attempts to demonstrate that the regulation does not render *21 U.S.C. § 355(j)(4)(B)(iv)(I)*

superfluous. Granutec and FDA cite legislative history in support of their argument that the regulation is consistent with the statute. However, both are mistaken. *Chevron* clearly states that [HN9] the determination of a regulation's validity under its enabling statute involves a two-stage process. **[*20]** Analysis of legislative history and policy goals occurs at the *second* stage, and is reached only if Congress, through the relevant statute, has not spoken directly to the issue in question. *See Chevron, 467 U.S. at 842-43*. If Congress has so spoken, "that is the end of the matter," *id. at 842*; a court simply does not undertake to assess the reasonableness of the agency's interpretation of the statute if Congress has spoken.

Our examination of the regulation's relation to the statute never reaches the second stage in this case. Congress has plainly laid out the requirements for the 180-day exclusivity period in the statute (albeit in tortured language), and, thus, our inquiry into Congressional intent must end there. [HN10] Having found the exclusivity requirements embodied in the statutory language of *21 U.S.C.A. § 355(j)(4)(B)(iv)* clear and conclusive, we are bound to hold invalid any attempt to alter the terms of that statute.

[HN11] The "successful defense" requirement in *21 C.F.R. § 314.107(c)(1)* amounts to such an alteration because it adds a requirement to *21 U.S.C.A. § 355(j)(4)(B)(iv)* that Congress never contemplated. Further, the idea that any 180-day exclusivity period **[*21]** must be premised on the successful defense of an infringement suit results in the evisceration of *21 U.S.C.A. § 355(j)(4)(B)(iv)(I)*, which clearly contemplates an exclusivity period beginning -- whether or not an infringement suit has come to resolution -- on the date of first commercial marketing by the first ANDA filer.

Thus, we hold the "successful defense" requirement contained in *21 C.F.R. § 314.107(c)(1)* to be an invalid addition to the statutory requirements for exclusivity. Genpharm, as the first ANDA filer, was therefore entitled to a period of exclusivity under the statute. [1]

> 1 We reject Geneva's argument that Genpharm lost its place in line as the first ANDA applicant, and thus the only ANDA applicant, eligible for exclusivity. FDA maintains that, although Genpharm did not make the Paragraph IV certification relevant to these proceedings until 1996, Genpharm qualifies as the first ANDA applicant [HN12] for purposes of the exclusivity because the certification relates back to the date of its ANDA application. This interpretation does not clearly conflict with either the regulations or the statute, and thus we find no reason to substitute a contrary judgment on this matter for that of FDA. *See Chevron, 467 U.S. at 843-45*; *Pauley v. Beth Energy Mines, Inc., 501 U.S. 680, 696-98, 700-06, 115 L. Ed. 2d 604, 111 S. Ct. 2524 (1991)*; *Mullins Coal Co. v. Director, OWCP , 484 U.S. 135, 159, 98 L. Ed. 2d 450, 108 S. Ct. 427 (1987)*; *Lisa Lee Mines v. Director, OWCP, 86 F.3d 1358, 1360-63 & n.8 (4th Cir. 1996)*.

[*22] B.

Having concluded that the "successful defense" requirement imposed by *21 C.F.R. § 314.107(c)(1)* is invalid, we turn now to determine how to measure Genpharm's period of exclusivity. This determination depends upon the interpretation given to the phrase "the date of a decision of a court" holding the patent invalid or not infringed, as used in *21 U.S.C.A. § 355(j)(4)(B)(iv)(II)*. The litigants (and amicus Boehringer Ingelheim Corp.) espouse multiple interpretations of the phrase, and, accordingly, suggest just as many different dates from which to measure exclusivity.

FDA has adopted alternative positions regarding how to interpret this provision, depending upon our decision with regard to the validity of the "successful defense" requirement. If we upheld the "successful defense" requirement found in *21 C.F.R. § 314.107(c)(1)*, FDA argued that, pursuant to the language of that regulation, we should conclude "*a* court" means " *the* court" that rendered the "successful defense" decision for the first ANDA applicant. Thus, no litigant would be entitled to exclusivity because the only litigant ever possibly entitled was Genpharm, and Genpharm had not successfully defended when **[*23]** Granutec sought approval of its ANDA effective July 10.

However, in the event that we found the "successful defense" requirement invalid, as we have, FDA adheres to the argument consistent with its original position in this suit, reflecting its acquiescence in *Mova*. That is, the "successful defense" requirement being invalid, FDA argues that "*a* court" means " *any* court." By this reasoning, Genpharm's exclusivity began running at the date of a decision by the first court to hold the *431 patent* not infringed, whether or not that decision involved Genpharm (the first ANDA applicant).

FDA then combines this reasoning with the terms of *21 C.F.R. § 314.107(e)*. [HN13] "For purposes of establishing the effective date of approval," that section defines "a decision of a court" in terms of a "final judgment from which no appeal can be or has been taken." *Section 314.107(e)* goes on to state that "the date of final decision" shall be, in the case of no appeal by the patent holder, "the date on which the right to appeal lapses," and, in the case of an appeal, "the date of the first decision or order by a higher court" affirming the district court's non-infringement decision. *21 C.F.R. §* **[*24]** *314.107(e) (1997)*. Thus, FDA concludes that Gen-

pharm's period of exclusivity ran from March 3, 1997 -- the date that Glaxo's right of appeal lapsed in the *Boehringer Ingelheim* suit [2] -- and expired 180 days later on August 29, 1997.

2 Genpharm contends that Glaxo did appeal the district court's order, and thus March 3, 1997, is an improper date to measure from even under FDA's analysis. We disagree. By order dated October 7, 1996, the district court in the *Boehringer* suit granted partial summary judgment to Boehringer on the basis of Glaxo's express concession that Boehringer's generic did not infringe the *431 patent*. Thereafter, on November 18, 1996, the court entered partial summary judgment in Boehringer's favor on Glaxo's claim that Boehringer infringed Glaxo's patents by filing its ANDA. On January 30, 1997, the court entered final judgment with regard to both of these orders. *See Glaxo, Inc. v. Boehringer Ingelheim Corp., 962 F. Supp. 295 (D. Conn. 1997)*. Glaxo appealed that judgment and lost, *see 119 F.3d 14, 1997 WL 355339 (Fed. Cir. 1997)*; however, it appealed only with regard to the November 18 order, not the October 7 order that the district court entered on the basis of Glaxo's express concession of non-infringement. *See id.* at n.1; *see also* Memorandum of Genpharm, Inc., in Support of its Mot. for an Inj. Pending Appeal, at Tab 4 (Aug. 18, 1997) (copy of letter from attorney for Glaxo to attorney for Boehringer Ingelheim declaring that "Glaxo is not appealing the Court's October 7, 1996 decision").

[*25] Although FDA's "successful defense" regulation was an invalid attempt to impose an additional requirement in derogation of the statutory scheme, FDA's reading of "the date of a decision of a court" simply interprets *ambiguous* statutory terminology. Despite the corporate litigants' arguments and protests to the contrary, this statutory language possesses no clear, definite meaning. For the purpose of measuring exclusivity under this statutory scheme, "the date of a decision" may mean the date of a district court decision, but it may also mean -- without, contrary to Granutec's suggestion, doing harm to ordinary principles of finality and res judicata-- the date appeal rights lapse or the date a higher court renders its first decision, as FDA's regulation contemplates. Similarly, " a court" may mean "the court," but it may just as well mean "any court." A fair reading of this statutory language does not clearly dictate a particular interpretation.

Each version bears certain problems in relation to the statutory scheme. At first blush, FDA's preferred interpretation (if the "successful defense" requirement is invalid) achieves a seemingly anomalous result in that a first applicant **[*26]** (here, Genpharm) receives an entitlement to exclusivity during a period when, presuming the imposition of a 30-month stay under *21 U.S.C.A. § 355(j)(4)(B)(iii)*, that applicant may not be able to take advantage of its exclusive rights until the 30-month period ends or it receives a favorable non-infringement judgment. However, this interpretation seeks to thwart any attempt by pioneer drug manufacturers to capture the generic market, and to some degree achieves that goal. Furthermore, although FDA's interpretation subjects first applicants to the vagaries of timing and speed attributable to different courts, it does not strip exclusivity of all value. As Genpharm and Granutec have demonstrated, the ability to waive exclusivity in favor of another generic manufacturer can be quite lucrative.

By contrast, Genpharm and Geneva contend that "a court" must mean "the court," and thus each maintains that the period of exclusivity cannot begin to run until the generic manufacturer entitled to exclusivity begins marketing or wins a patent infringement suit brought against it by the pioneer manufacturer. This interpretation preserves exclusivity for the first applicant until it prevails in litigation, **[*27]** or at least until it begins marketing while assuming the risk of losing the litigation. However, it clears the way for generic capture.

Such a result would be antithetical to the very purpose of the exclusivity incentive and the entire ANDA regime. As the legislative history of the Hatch-Waxman amendments indicates, the ANDA scheme purports to "make available more low cost generic drugs." H.R. Rep. No. 98-857, pt. 1, 98th Cong., 2d Sess., at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647. A situation where no generic can come to market because the pioneer has imposed a stranglehold by gaining entitlement to an exclusive marketing period for its captured generic, yet never exercises that right, could not have been contemplated by Congress. [3]

3 We recognize that even under FDA's interpretation a pioneer could place a stranglehold on the generic market, although we think it is less likely. For example, a pioneer in control of a captured generic could file the first ANDA with a Paragraph IV certification. As long as the pioneer prevents its captured generic from going to market and at the same time does not file an infringement suit against *any* generic manufacturer (captured or non-captured), the captured generic's exclusivity period would never begin to run, and no generic could begin to sell pursuant to a Paragraph IV certification. The "successful defense" requirement would solve this problem, were it valid. But this problem, like many others, arises

from the manner in which Congress drafted the exclusivity mechanism, and, as such, the remedy lies with Congress.

[*28] Given the complicated and sensitive nature of the statutory drug approval mechanism, we choose to defer to the interpretation posited by the agency charged by Congress with administering the statutory scheme. [HN14] FDA's interpretation of the statutory language and its own regulations is a permissible, reasonable interpretation of a complicated legislative framework that reflects a considered balance of competing statutory goals. We recognize that positions adopted by an agency solely for litigation do not deserve the deference of this Court. *See Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 213, 102 L. Ed. 2d 493, 109 S. Ct. 468 (1988)* ("Deference to what appears to be nothing more than an agency's convenient litigating position would be entirely inappropriate."). However, we are not faced with such a situation here. FDA did not adopt its current position in anticipation of this litigation, but in response to the *Mova* decision, which suggested the probable invalidity of the "successful defense" requirement. It made its position known to all ANDA applicants seeking approval in the wake of *Mova*, seeking to avoid any forum shopping that might result. Indeed, it was FDA's adherence **[*29]** to its post-*Mova* position that precipitated this lawsuit by Granutec. In such a situation, the concerns that caution against deference to an agency's litigation position do not exist because the position reflects the thoughtful judgment of the agency, not just the posture of litigation counsel. *See National Wildlife Fed'n v. Browner, 326 U.S. App. D.C. 451, 127 F.3d 1126, 1129 (D.C. Cir. 1997)* (citing *Auer v. Robbins, 519 U.S. 452, 137 L. Ed. 2d 79, 117 S. Ct. 905, 912 (1997)*); *Herman v. NationsBank Trust Co., 126 F.3d 1354, 1363 (11th Cir. 1997)*; *Appalachian States Low-Level Radioactive Waste Comm'n v. Pena, 126 F.3d 193, 198-99 (3rd Cir. 1997)*; *Monongahela Power Co. v. Reilly, 980 F.2d 272, 279 & n.7 (4th Cir. 1993)*.

C.

Both Genpharm and Geneva also assert jurisdictional and procedural grounds for reversal of the district court-- namely, that the district court lacked subject matter jurisdiction over this case and failed to give the intervenors the proper notice and hearing before dismissing the cross-claims and granting, *sua sponte* , a permanent injunction.

We would have jurisdiction if the district court lacked it, and thus all appellants have received the remedy **[*30]** they seek-- a full hearing and decision on the merits in the Court of Appeals. In addition, if we held that the district court failed to provide proper notice and hearing to the parties, the remedy would be to remand to the district court for largely the same proceedings that we have conducted.

For these reasons, we reject these allegations of procedural shortcomings on the part of the district court.

III.

In sum, then, we hold that the "successful defense" requirement imposed by *21 C.F.R. § 314.107(c)(1)* is invalid. Further, we hold that, under the interpretation of the statutory scheme adopted by the FDA in contemplation of such a decision, Genpharm was entitled to a period of exclusivity that ran from March 3, 1997, until August 29, 1997. Because Genpharm waived its exclusivity with regard to Granutec, and FDA approved Geneva's ANDA as of August 29, 1997, no party has violated Genpharm's period of exclusivity. Granutec was never entitled to begin marketing on July 25, 1997, so its agreement with Glaxo to begin marketing on July 10, 1997, was based on an erroneous premise. The supersedeas bonds shall be returned, along with accrued interest, to Genpharm and Geneva.

We understand **[*31]** this opinion will not satisfy any party to this suit. In cases involving complicated regulatory schemes such as this, we seek to give full effect to the plain language of a statute while simultaneously deferring to reasonable interpretations offered by the relevant federal agency. The complex legislative scheme and the awkwardly drafted statute at issue here do not lend themselves to simple solutions, particularly when further complicated by secondary licensing arrangements, a stay pending appeal, and multi-million dollar bonds. In accordance with this opinion, the judgment of the district court is hereby

REVERSED.

EXHIBIT "B"

LEXSEE 2007 U.S. APP. LEXIS 6447

BAPTIST PHYSICIAN HOSPITAL ORGANIZATION, INC. and BAPTIST HOSPITAL OF EAST TENNESSEE, INC., Plaintiffs-Appellees, v. HUMANA MILITARY HEALTHCARE SERVICES, INC., Defendant-Appellant.

No. 06-5364

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

07a0107p.06; *481 F.3d 337*; *2007 U.S. App. LEXIS 6447*

January 31, 2007, Argued
March 21, 2007, Decided
March 21, 2007, Filed

PRIOR HISTORY: [**1] Appeal from the United States District Court for the Eastern District of Tennessee at Knoxville. No. 01-00588--Thomas W. Phillips, District Judge.
Baptist Physician Hosp. Org., Inc. v. Humana Military Healthcare Servs., 415 F. Supp. 2d 835, 2006 U.S. Dist. LEXIS 8968 (E.D. Tenn., 2006)

DISPOSITION: The district court's order was affirmed.

LexisNexis(R) Headnotes

Healthcare Law > Managed Healthcare > Health Maintenance Organizations
[HN1] Diagnostic related groups (DRGs) are a method of dividing hospital patients into clinically coherent groups based on the consumption of resources. *32 C.F.R. § 199.2*. Patients are assigned to the groups based on their principle diagnosis (the reason for admission, determined after study), secondary diagnoses, procedures performed, and the patient's age, sex, and discharge status.

Administrative Law > Judicial Review > Standards of Review > Rule Interpretation
Governments > Legislation > Interpretation
[HN2] As with all matters of regulatory interpretation, a court must look first to the plain and unambiguous meaning of the regulation, if any. Courts read statutes and regulations with an eye to their straightforward and commonsense meanings, and where the regulation's language reveals an unambiguous and plain meaning the court's task is at an end.

Healthcare Law > Managed Healthcare > Health Maintenance Organizations
Military & Veterans Law > General Overview
[HN3] See *32 C.F.R. § 199.17(a)(1)*.

Healthcare Law > Managed Healthcare > Health Maintenance Organizations
Military & Veterans Law > General Overview
[HN4] While managed care contractors may enter into special arrangements with preferred network providers consistent with the "special rules and procedures" set forth in the TRICARE regulations, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), regulations remain effective and applicable to TRICARE providers unless the special rules and procedures state otherwise.

Healthcare Law > Managed Healthcare > Health Maintenance Organizations
Military & Veterans Law > General Overview
[HN5] Federal regulations permit all Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), providers to receive capital payments to offset the costs of treating CHAMPUS beneficiaries. *32 C.F.R. § 199.14(a)(1)(iii)(G)*. Under *32 C.F.R. § 199.14*, a TRICARE preferred network provider is not rendered ineligible for capital payments merely because they have negotiated an "alternative payment methodology" for reimbursement. Regulations implementing the TRICARE Program provide that where rules, procedures, rights and obligations under TRICARE differ from those under CHAMPUS, those set forth in the TRICARE regu-

lations take precedence and are binding. *32 C.F.R. § 199.17(a)(4)*.

Healthcare Law > Insurance > Reimbursement > General Overview
Healthcare Law > Managed Healthcare > Health Maintenance Organizations
[HN6] See *32 C.F.R. § 199.14(a)(1)(iii)(G)(1)*.

Healthcare Law > Managed Healthcare > Health Maintenance Organizations
Military & Veterans Law > General Overview
[HN7] With regard to payment of health providers under the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), neither the statute nor the regulations reveal a relevant distinction between an "MSC prime contractor" and an "MSC contractor" more generally. The statutory provisions that, in part, establish the TRICARE program define "TRICARE Prime" as the managed care option of the TRICARE program. *10 U.S.C.S. §§ 1079(g)(5), 1097a(f)(1)*. Although those provisions make the definition applicable only to those sections, no more generally applicable definition of TRICARE Prime exists in the current statute or regulations. Nor do the statute or regulations define "MSC Prime Contractor." The TRICARE Reimbursement Manual lends further support to this view in clarifying that the MCS Contractor is responsible for all TRICARE Prime.

Healthcare Law > Managed Healthcare > Health Maintenance Organizations
Military & Veterans Law > General Overview
[HN8] Traditional Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), reimbursement methods, permit payment of capital costs along with additional payments for outlier cases. *32 C.F.R. § 199.14(a)(1)*. Specifically, the regulations provide reimbursement greater than the standard Diagnostic related group (DRG)-rate for cost outliers and for length-of-stay outliers. *32 C.F.R. § 199.14(a)(1)(iii)(E)(1)(ii)* provides additional payment for any discharge which has standardized costs that exceed an established threshold. *32 C.F.R. § 199.14(a)(1)(iii)(E)(1)(i)* states that additional payment for any discharge which has a length-of-stay (LOS) exceeding a threshold established. The additional outlier payment in no way diminishes the provider's entitlement to capital payments under the same regulatory provision. *32 C.F.R. § 199.14(a)(1)(iii)(G)*.

Healthcare Law > Managed Healthcare > Health Maintenance Organizations
Military & Veterans Law > General Overview
[HN9] The regulations implementing the Supplemental Care Program acknowledge that the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), provider reimbursement regulations generally will guide payment and administration of Supplemental Care claims. *32 C.F.R. § 199.16(c)*. However, the regulations further establish exceptions and clarifications to the general rule. *32 C.F.R. § 199.16(d)*. Specifically, the regulations clarify that annual cost pass-throughs for capital costs that are available under the CHAMPUS Diagnostic related group (DRG)-based payment system are also available, upon request, under the supplemental care program. *32 C.F.R. § 199.16(d)(4)*. Notwithstanding the entitlement to capital payments, that same subsection goes on to clarify that for some providers, payment in excess of CHAMPUS allowable amounts may be authorized. *32 C.F.R. § 199.16(d)(5)*. Accordingly, the Supplemental Care Program regulations demonstrate that The Department of Defense contemplated simultaneous entitlement to capital payments and payments exceeding typical CHAMPUS allowable amounts.

Healthcare Law > Managed Healthcare > Health Maintenance Organizations
Military & Veterans Law > General Overview
[HN10] The United States Court of Appeals for the Sixth Circuit holds that the regulations authorize capital payments to TRICARE preferred network providers regardless of the methodology employed to reimburse claims for inpatient care -- whether it be the Diagnostic related group (DRG)-based system, or some alternative.

Healthcare Law > Managed Healthcare > Health Maintenance Organizations
Military & Veterans Law > General Overview
[HN11] See *32 C.F.R. § 199.14(a)(1)(ii)(D)*.

Healthcare Law > Managed Healthcare > Health Maintenance Organizations
Military & Veterans Law > General Overview
[HN12] Typically, only hospital units exempt from the Medicare Prospective Payment System are exempt from the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), Diagnostic related group (DRG)-based payment system. *32 C.F.R. § 199.14(a)(1)(ii)(D)(1)-(5)*. Additionally, all hospitals subject to the CHAMPUS DRG-based payment system may be reimbursed for allowed capital costs by submit-

ting a request to the CHAMPUS contractor. *32 C.F.R. § 199.14(a)(1)(iii)(G)(3)*.

Healthcare Law > Managed Healthcare > Health Maintenance Organizations
Military & Veterans Law > General Overview
[HN13] The capital payment provision of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), regulations lists the information required in order to verify the appropriate capital payment amount. Among this list, the regulation directs providers to submit total inpatient days provided to all patients in units subject to Diagnostic related group (DRG)-based payment and total allowed CHAMPUS inpatient days provided in units subject to DRG-based payment. *32 C.F.R. § 199.14(a)(1)(iii)(G)(3)(vi)-(vii)*. The regulations notably do not define "DRG-based payment." Nor do the regulations clarify whether "DRG-based payment" in the former context refers collectively to Medicare and CHAMPUS inpatients, to some broader group, or to CHAMPUS alone.

Healthcare Law > Managed Healthcare > Health Maintenance Organizations
Military & Veterans Law > General Overview
[HN14] All costs reported to a Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), contractor must correspond to the costs reported on the hospital's Medicare cost report. *32 C.F.R. § 199.14(a)(1)(iii)(G)(3)*. The term "Diagnostic related group (DRG)-rate" originated in Medicare. *32 C.F.R. § 199.14(a)(1)(i)(A)*.

Healthcare Law > Managed Healthcare > Health Maintenance Organizations
Military & Veterans Law > General Overview
[HN15] The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), regulations were never thoroughly amended following implementation of the TRICARE program to allow for the possibility that MCS contractors would enter into alternative payment arrangements with health care providers in their networks. In fact, the Department of Defense (DOD) Final Rule implementing the TRICARE program proves as much. *32 C.F.R. § 199.17*. The regulatory approach is to leave the existing CHAMPUS rules largely intact and to create new *32 C.F.R. §§ 199.17* and *199.18* to describe the TRICARE Program and the uniform HMO benefit.

Civil Procedure > Appeals > Standards of Review > De Novo Review
[HN16] An appellate court reviews a district court's conclusions of law de novo.

Contracts Law > Contract Modifications > General Overview
[HN17] In Tennessee, the parties to an existing contract can modify its terms at any time. However, an existing contract cannot be unilaterally modified. Rather, valid modification requires the same mutuality of assent and meeting of the minds as required to make a contract in the first instance. Additionally, consideration must be exchanged to effect modification of an existing contract. Performing what was already promised in the original contract is not consideration to support a second contract.

Healthcare Law > Managed Healthcare > Health Maintenance Organizations
Military & Veterans Law > General Overview
[HN18] *32 C.F.R. § 199.14(a)(1)(iii)(G)(3)* states that the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), shall reimburse the hospital its share of actual capital costs.

Healthcare Law > Managed Healthcare > Health Maintenance Organizations
Military & Veterans Law > General Overview
[HN19] With regard to payment of health providers under the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), for payment of pass through costs, the contractor provides information to Department of Defense (DOD) to seek approval for payment. If the DOD approves payment, the contractor is notified to pay the claim.

Civil Procedure > Pleading & Practice > Defenses, Demurrers, & Objections > Waiver & Preservation
[HN20] Waiver is the knowing and intentional relinquishment or abandonment of a known right. There can be no effective waiver of rights where a party either does not know its rights or fails to fully understand those rights. Put another way, intent to waive is required. Waiver may be proved by express declaration; or by acts and declarations manifesting an intent and purpose not to claim the supposed advantage; or by a course of acts and conduct. Where a party seeks to prove waiver by course of conduct, there must be clear, unequivocal and decisive acts of the party or an act which shows determination not to have the benefit intended in order to constitute a waiver.

Civil Procedure > Appeals > Reviewability > Preservation for Review
[HN21] The courts of appeals are not self-directed boards of legal inquiry and research, but essentially arbiters of legal questions presented and argued by the parties. Issues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.

Civil Procedure > Pleading & Practice > Defenses, Demurrers, & Objections > Affirmative Defenses
[HN22] Equitable defenses may bar purely legal claims. To successfully invoke the doctrine of laches, a defendant must show an inexcusably long delay in commencing the action which causes prejudice to the other party, and mere delay will not suffice. A finding of sufficient prejudice frequently follows from the death of witnesses, the loss of evidence, or failure of memory resulting in obscuration of facts which render uncertain the ascertainment of truth, and make it impossible for the court to pronounce a decree with confidence.

Contracts Law > Remedies > Avoidable Consequences
[HN23] The party alleging breach of contract has a legal duty to exercise reasonable and ordinary care under the circumstances to prevent and diminish the damages. Although the injured party must take "reasonable and ordinary" steps to mitigate, one is not required to make extraordinary efforts.

Civil Procedure > Remedies > Judgment Interest > Prejudgment Interest
Civil Procedure > Appeals > Standards of Review > Abuse of Discretion
[HN24] On review, challenges to a district court's award of prejudgment interest will not be disturbed unless the record reveals a manifest and palpable abuse of discretion.

Civil Procedure > Remedies > Judgment Interest > Prejudgment Interest
[HN25] Where consistent with principles of justice and equity, the Tennessee Code provides for the award of prejudgment interest at a rate not to exceed 10 percent per annum. *Tenn. Code Ann. § 47-14-123.* First and foremost, principles of equity guide trial courts in exercising their discretion to award prejudgment interest. Second, a trial court will more readily award prejudgment interest when the amount of the obligation is certain, or can be ascertained by proper accounting. Third, interest is allowed when the existence of the obligation itself is not disputed on reasonable grounds. While useful as guideposts, the Tennessee Supreme Court has observed that these criteria have not been used to deny prejudgment interest in every case where the defendant reasonably disputed the existence or amount of an obligation.

COUNSEL: ARGUED: Michael J. Kitchen, J. BRUCE MILLER LAW GROUP, Louisville, Kentucky, for Appellant. Reuben N. Pelot IV, EGERTON, McAFEE, ARMISTEAD & DAVIS, Knoxville, Tennessee, for Appellees.

ON BRIEF: Michael J. Kitchen, J. Bruce Miller, J. BRUCE MILLER LAW GROUP, Louisville, Kentucky, for Appellant. Reuben N. Pelot IV, Cheryl G. Rice, EGERTON, McAFEE, ARMISTEAD & DAVIS, Knoxville, Tennessee, for Appellees.

JUDGES: Before: NORRIS, COLE, and CLAY, Circuit Judges.

OPINION BY: CLAY

OPINION

[*339] CLAY, Circuit Judge. In this appeal, Defendant, Humana Military Healthcare Services, Inc., appeals the district court's order finding Defendant liable to Plaintiffs, Baptist Physician Hospital Organization, Inc. and Baptist Hospital of East Tennessee, Inc., for breach of contract and awarding Plaintiffs $ 1,277,872.90 in compensatory damages, as well as $ 731,488.65 in prejudgment interest. Plaintiffs properly invoke diversity of citizenship as the basis for federal jurisdiction in this case. *See 28 U.S.C. § 1332.* For the reasons that follow, **[**2]** we **AFFIRM** the district court's order.

BACKGROUND

This Tennessee breach of contract suit was previously before this Court. *See Baptist Physician Hosp. Org., Inc. v. Humana Military Healthcare Servs., Inc., 368 F.3d 894 (6th Cir. 2004)* (hereinafter "*Baptist Physician I*"). That appeal arose when the district court granted summary **[*340]** judgment to Defendant on Plaintiffs' breach of contract claim, and separately dismissed Plaintiffs' remaining claims as untimely. On appeal, this Court reversed and remanded.

Baptist Physician I aptly set forth background relevant to the initial contract between the parties:

> Pursuant to authority delegated to it by Congress, the Department of Defense established the Civilian Health and Medical Program of the Uniformed Services,

called CHAMPUS, in 1967. CHAMPUS beneficiaries include retired armed forces personnel and dependents of both active and retired military personnel. In 1995, the Department of Defense established TRICARE, a managed health care program operating as a supplement to CHAMPUS and involving the competitive selection of private contractors to financially underwrite the delivery of health care services **[**3]** under CHAMPUS. The overall goal of the TRICARE program is to improve the quality, cost, and accessibility of healthcare to the nation's military through the mechanism of a managed care program, and one aspect of the new TRICARE program was the establishment of "Civilian Preferred Provider Networks." *See 32 C.F.R. § 199.17(p).* TRICARE Management Activity, which was previously known as Office of CHAMPUS, is the government office charged with the responsibility of administering TRICARE/CHAMPUS.

In January 1996, Humana Military Healthcare Services, Inc. was awarded the TRICARE contract for Regions 3 and 4, which covers seven states and includes the State of Tennessee. Under the contract, Humana became the managed care support contractor charged with the responsibility of establishing and managing a Civilian Preferred Provider Network throughout the seven state area. Humana established the preferred provider network by entering into contractual arrangements with individual CHAMPUS participating providers of medical services, one of which was Baptist. Broadly speaking, TRICARE preferred network providers agreed to accept from a managed care support contractor **[**4]** lower reimbursement rates than those authorized under the CHAMPUS reimbursement system, with the understanding that in exchange they would see an increase in directed volume. These discounted rates might be expressed as discounts from the maximum allowable rate under the CHAMPUS diagnostic grouping system (DRG), [1] or as a fixed per diem rate, or as some other agreed-upon rate of reimbursement.

> In the early spring of 1996, Baptist Physician Hospital Organization, Inc. and Baptist Hospital of East Tennessee, or more simply "Baptist," entered into negotiations with Humana to become a TRICARE preferred network provider.

Baptist Physician I, 368 F.3d at 895-97.

> 1 [HN1] Diagnostic related groups (DRGs) are "a method of dividing hospital patients into clinically coherent groups based on the consumption of resources." *32 C.F.R. § 199.2.* "Patients are assigned to the groups based on their principle [sic] diagnosis (the reason for admission, determined after study), secondary diagnoses, procedures performed, and the patient's age, sex, and discharge status." *Id.*

[5]** At trial, the parties presented a more detailed picture of their relationship preceding, during, and subsequent to executing the Letter of Agreement (hereinafter "Agreement"), by which Plaintiffs contracted to provide care to TRICARE beneficiaries in Defendant's network. [2] On **[*341]** August 6, 1996, Defendant's Director of Network Development, Richard Mancini ("Mancini"), signed the Agreement on Defendant's behalf. Therein, Defendant contracted to reimburse Plaintiffs according to the terms of a "Hospital Payment Arrangement." As the court in *Baptist Physician I* explained, the parties adopted

> a three-tiered system of discounted reimbursement from the CHAMPUS rates depending on the number of other TRICARE providers in the area . . . . [T]he "Hospital Payment Arrangement" . . . was expressed as a percentage discount off the CHAMPUS DRG reimbursement rate with a "stop loss" provision (in the italicized language below) consisting of an increased rate of payment for certain high-dollar inpatient claims as an alternative to a percentage discount from standard government rates. The purpose of the stop-loss provision is to reduce the risk of losses to Baptist in large individual **[**6]** cases that Baptist believed the percentage discount off CHAMPUS DRG rates would create. The contractual provision was expressed as follows:
>
> **Baptist Health System as Exclusive Provider**

Inpatient

20% Discount from CHAMPUS DRG rates;

Any case with provider charges greater than $ 30,000 reverting to a 45% discount from provider charges.

Outpatient

30% Discount from CHAMPUS allowables.

Baptist Health System + 1 Additional Provider

Inpatient

20% Discount from CHAMPUS DRG rates;

Any case with provider charges greater than $ 25,000 reverting to a 35% discount from provider charges.

Outpatient

25% Discount from CHAMPUS allowables.

Baptist Health System + 2 Additional Providers

Inpatient

15% Discount from CHAMPUS DRG rates;

Any case with provider charges greater than $ 25,000 reverting to a 30% discount from provider charges.

Outpatient

25% Discount from CHAMPUS allowables.

(Emphasis added.) Under each tier, Baptist and Humana agreed to the "stop loss" language which increased reimbursement to Baptist when a particular inpatient [**7] hospital stay exceeded a certain dollar amount. In such cases, the reimbursement rate would not be a percentage discount off the CHAMPUS DRG rate, but rather would "revert" to a percentage discount off the provider charges, which are the charges the hospital would otherwise charge for the services rendered.

An example illustrates how the "stop loss" provision would work. Suppose a certain hospital stay resulted in provider charges of $ 77,098, but the maximum CHAMPUS DRG reimbursement rate for this particular stay is only $ 27,755.00. Without the stop loss provision, Baptist as the exclusive TRICARE provider under the above agreement would receive $ 22,204, which represents a 20% discount from the CHAMPUS DRG rate and an effective 71% discount from provider charges. Under the stop loss provision, however, Baptist would receive $ 42,404, or a 45% discount from **[*342]** the provider charges. In effect, the stop loss provision operates to increase the net overall discount for the business associated with the TRICARE program.

As illustrated above, for certain claims the reimbursement amount calculated as a percentage of provider charges was greater than 100% of the CHAMPUS DRG rate. **[**8]**

Baptist Physician I, 368 F.3d at 896-97. At the time he signed the Agreement, Mancini knew Defendant had no intention of paying the stop loss claims pursuant to the Agreement inasmuch as they exceeded CHAMPUS allowable charges.

2 We are largely guided in our narrative by the district judge's findings of fact, which we find -- with one insignificant exception -- were not clearly erroneous. *See Kalamazoo River Study Group v. Rockwell Int'l Corp., 355 F.3d 574, 589 (6th Cir. 2004).*

Two days after he executed the Agreement, in an August 8, 1996 letter to Plaintiffs' representative, Jim Goodloe, Mancini wrote as follows:

Jim, as we move toward the next round of negotiations, specifically: Inpatient per diem rates, I want to make sure we both

> understand that your claims will be paid according to a discount from Government allowables. I know there has been some question that you wanted to be paid more than the Government provides, but we aren't allowed to pay your **[**9]** facilities any greater than the non-network rate. Accordingly, the per diem rates that we agree upon will need to be comparable as provided for in paragraph M of our contract.

Baptist Physician Hosp. Org., Inc. v. Humana Military Healthcare Servs., Inc., 415 F. Supp. 2d 835, 848 (E.D. Tenn. 2006) (hereinafter "*Baptist Physician II*"). The district court found that this letter concerned physician reimbursement terms, and not the stop loss provisions. [3]

> 3 In fact, the district court found that the parties amended the physician payment provisions in September 1996, but that those amendments did not impact hospital reimbursement for stop loss claims.

The Agreement contemplated additional negotiations in September 1996 to establish a system of reimbursement on a per diem basis and, at trial, Mancini testified that he believed that the parties would have dispensed with the stop loss provisions at that time. No subsequent renegotiation occurred, and the stop loss provisions remained **[**10]** in effect throughout the life of the Agreement. Mancini further testified that Defendant did not pursue renegotiation because the process would have clarified that Defendant intended to cap payments at government allowables, and not to pay according to the Agreement.

In August 1996, Plaintiffs lacked the personnel and technology necessary to closely monitor payments from third party payors, including Defendant, to insure payment of submitted claims according to negotiated contract terms. However, over the course of the Agreement with Defendant, Plaintiffs took steps to improve claims tracking. To start, Plaintiffs purchased software (called "PCMS") capable of auditing payments and exposing payment variances. This software required Plaintiffs to load their contracts into the system before it could adequately monitor payment compliance. Plaintiffs also hired a contract analyst, Anahita Hodge ("Hodge"), primarily assigning her to scrutinize payments from third party payors. Ultimately, Plaintiffs loaded their contract with Defendant into the PCMS system in November 1998.

In early 1999, Hodge identified the underpaid stop loss claims and, in February 1999, requested that Defendant reprocess **[**11]** the claims in compliance with the terms of the Agreement. In a July 22, 1999 letter to Defendant's government benefits administrator, Hodge again requested the additional stop loss reimbursement. Subsequently, Hodge spoke to Carmen Montanez **[*343]** ("Montanez"), then one of Defendant's employees, who informed her that Defendant would not pay the full stop loss amount on the contested claims. During the conversation, Montanez cited the TRICARE / CHAMPUS policies and procedures and told Hodge that those policies foreclosed Defendant from paying rates in excess of the CHAMPUS DRG-rates. In the months that followed, Plaintiffs at no point communicated to Defendant an intent to drop the stop loss claims. Ultimately, Defendant sent Plaintiffs a letter on February 5, 2001 notifying Plaintiffs that it was exercising its right to terminate the Agreement, effective May 6, 2001. Defendant terminated the Agreement due to Plaintiffs' continued insistence that they be reimbursed according to the Agreement's stop loss provisions.

Between July 1, 1996 and May 6, 2001 -- the life of the Agreement -- 85 inpatient claims for medical care rendered at Plaintiffs' facilities exceeded the stop loss threshold. In **[**12]** each instance, Plaintiffs did not receive reimbursement according to the stop loss provisions. Rather, without Plaintiffs' knowledge, Defendant capped reimbursement at 100% of the CHAMPUS DRG-rate. Applying the stop loss provisions of the Agreement, Plaintiffs should have received $ 2,595,294.94 in payment of those claims. In actuality, Defendant paid only $ 1,317,422.05, thus yielding an underpayment of $ 1,277,872.89 on the stop loss claims. [4]

> 4 The district court additionally found facts relevant to Defendant's counterclaim that it had overpaid Plaintiffs for a number of outpatient claims by misapplying the "tier" system established in the Agreement. On appeal, Defendant waives its challenge to the district court's dismissal of its counterclaim. Accordingly, we need not further explore the circumstances of Defendant's overpayment.

The district court considered several issues at trial on remand, including: (1) whether the parties modified the Agreement so that high-dollar claims would be paid under the **[**13]** CHAMPUS DRG-based payment system as opposed to the stop loss provisions; (2) whether Plaintiffs waived their claims; (3) whether equitable doctrines barred Plaintiffs' claims; and (4) whether Defendant was entitled to recover alleged overpayments on outpatient claims. Ultimately, the district court ruled in favor of Plaintiffs on their breach of contract claim, and against Defendant on its defenses of modification, estoppel, failure to mitigate damages, and laches. The district

court further found that Defendant failed to prove damages, a required element of its counterclaim. In an opinion dated February 13, 2006, the district court awarded Plaintiffs $ 1,277,872.90 on their breach of contract claim, along with prejudgment interest totaling $ 731,488.65. Defendant timely appealed.

DISCUSSION

I. THE DISTRICT COURT DID NOT ERR IN DEEMING CAPITAL REIMBURSEMENT EVIDENCE IRRELEVANT

As a matter of law, the district court concluded that "[t]he monies paid to [Plaintiffs] pursuant to Capital Reimbursements are totally irrelevant to the Agreement at issue, would have been paid with or without an agreement between the parties, and were not paid pursuant to the Agreement. **[**14]** " *Baptist Physician II, 415 F. Supp. 2d at 853*. Defendant vehemently disagrees and, in fact, rests the weight of its appeal on this very question. Because the district court's disposition does not elucidate the rationale underlying its conclusion that capital payment evidence was irrelevant, we review the matter *de novo* **[*344]** as a conclusion of law. , 355 F.3d at 589*Kalamazoo River Study Group* [5].

> 5 In the alternative, we could construe this as a ruling on the admissibility of the capital payment evidence and, accordingly, could review for abuse of discretion. *See Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999)*. Although the district court's review of the evidence presented at trial notably excludes reference to Defendant's proffered capital payment exhibits (Exhibits 54(A)-(K)), it does recount witness testimony on the issue. *See Baptist Physician II, 415 F. Supp. 2d at 841, 847*. Because we cannot say with certainty that the district court intended to rule on the admissibility of the capital payment exhibits, we err on the side of caution and apply the less deferential *de novo* standard of review.

[15]** The relevance of the proffered capital payment evidence substantially turns on a question of regulatory interpretation. That is, whether capital payments flow only to those preferred network providers subject to the DRG-based payment system, or whether providers which contract for alternative payment methodologies may also receive capital payments consistent with the TRICARE / CHAMPUS regulations. As a corollary, we must also consider the significance of certifications submitted to obtain capital payments, wherein providers document the total number of inpatient days "provided to all patients in units subject to DRG-based payment," as well as the "[t]otal allowed CHAMPUS inpatient days provided in units subject to DRG-based payment." *See 32 C.F.R. § 199.14(a)(1)(iii)(G)(3)(vi)-(vii)*.

[HN2] As with all matters of regulatory interpretation, we look first to the plain and unambiguous meaning of the regulation, if any. *See Henry Ford Health Sys. v. Shalala, 233 F.3d 907, 910 (6th Cir. 2000)* (quoting *Bartlik v. United States DOL, 62 F.3d 163, 165-66 (6th Cir. 1995)*) ("We read statutes and regulations with an eye to their straightforward **[**16]** and commonsense meanings," and where the regulation's language reveals an "unambiguous and plain meaning . . ., our task is at an end"). Defendant fails to identify provisions either in the applicable regulations or the authorizing statutes that plainly sets forth the meaning of the regulations. Nor could it, for the TRICARE / CHAMPUS regulations do not squarely address this question.

We next look to the regulatory scheme, reading the regulation in its entirety to glean its meaning. In so doing, we find that the TRICARE / CHAMPUS regulations do not preclude capital payments to preferred network providers which, by agreement with Managed Care Support ("MCS") Contractors, receive reimbursement for inpatient care under alternative payment methodologies. As detailed in the TRICARE regulations, [HN3]

> [t]he TRICARE program implements management improvements primarily through managed care support contracts that include special arrangements with civilian sector health care providers . . . . Implementation of these management improvements includes adoption of special rules and procedures not ordinarily followed under CHAMPUS . . . . This section establishes those special rules and procedures. **[**17]**

32 C.F.R. § 199.17(a)(1). [HN4] While managed care contractors may enter into special arrangements with preferred network providers consistent with the "special rules and procedures" set forth in the TRICARE regulations, CHAMPUS regulations remain effective and applicable to TRICARE providers unless the special rules and procedures state otherwise.

As CHAMPUS providers, by default, Plaintiffs were entitled to receive capital payments regardless of their Agreement with Defendant. [HN5] Federal regulations permit **[*345]** all CHAMPUS providers to receive capital payments to offset the costs of treating CHAMPUS beneficiaries. *See 32 C.F.R. § 199.14(a)(1)(iii)(G)*. [6] Under *32 C.F.R. § 199.14*, a TRICARE preferred network provider is not rendered ineligible for capital payments

merely because they have negotiated an "alternative payment methodology" for reimbursement. Regulations implementing the TRICARE Program provide that where "rules, procedures, rights and obligations" under TRICARE differ from those under CHAMPUS, those set forth in the TRICARE regulations "take precedence and are binding." *32 C.F.R. § 199.17(a)(4)* **[**18]** . Illustratively, the TRICARE Reimbursement Manual ("the Manual") cites to *32 C.F.R. § 199.14* as authority for its discussion of capital payments. Accordingly, where the TRICARE regulations do not explicitly conflict with the CHAMPUS regulations, those pre-existing regulations apply to TRICARE as well.

6 Specifically, the regulations state: [HN6]

> When requested in writing by a hospital, CHAMPUS shall reimburse the hospital its share of actual capital costs reported annually to the CHAMPUS fiscal intermediary. Payment for capital costs shall be made annually based on the ratio of CHAMPUS inpatient days for those beneficiaries subject to the CHAMPUS DRG-based payment system to total inpatient days applied to the hospital's total allowable capital costs. Reductions in payments for capital costs which are required under Medicare shall also be applied to payments for capital costs under CHAMPUS.

32 C.F.R. § 199.14(a)(1)(iii)(G)(1).

Defendant directs **[**19]** our attention to the section of the Manual that discusses adjustments to payment amounts, such as capital payments, and, specifically, to the introductory paragraph on 'Applicability.' There, the Manual states --

> This policy is mandatory for reimbursement of services provided by either network or non-network providers. However, alternative network reimbursement methodologies are permitted when approved by TMA *and specifically included in the network provider agreement.*

TRICARE / CHAMPUS Policy Manual, 6010.53-M, Ch. 6, Section 8 at I (*available at* J.A. at 1050 (emphasis added)) The Agreement at issue does not specifically include language excepting Plaintiffs from the category of providers typically eligible to receive capital payments under the regulations.

In fact, that same section of the Manual details the entitlement to, and procedures for payment of, capital costs. More specifically, it establishes the obligations of both the provider and the MCS contractor. In a subpart with the heading "Negotiated Rates," the Manual states:

> *If a contract* between the MSC prime contractor and a subcontractor or institutional network provider *does not specifically* **[**20]** *state the negotiated rate includes all costs that would otherwise be eligible for additional payment, such as capital* and DME, *the MCS prime contractor is responsible for reimbursing these costs* to the subcontractors and institutional network providers *if a request for reimbursement is made.*

Id. at III.B.4.d. (*available at* J.A. at 1058-59 (emphasis added)) Defendant, as the MCS contractor for its region, negotiated rates with Plaintiffs, an institutional network provider. [7] Consistent with the Manual, **[*346]** the Agreement *could have* expressly stipulated that payment at the negotiated rate would incorporate capital payments. The Agreement did not make Plaintiffs' receipt of reimbursement under the stop loss provisions conditional upon forbearance from receipt of capital payments. [8] Plaintiffs therefore remained entitled to receive capital payments notwithstanding the operation of the negotiated alternative to the DRG-based rates.

7 [HN7] Neither the statute nor the regulations reveal a relevant distinction between an "MSC prime contractor" and an "MSC contractor" more generally. The statutory provisions that, in part, establish the TRICARE program define "TRICARE Prime" as "the managed care option of the TRICARE program." *10 U.S.C. § 1079(g)(5)*; *10 U.S.C. § 1097a(f)(1)*. Although those provisions make the definition applicable only to those sections, no more generally applicable definition of TRICARE Prime exists in the current statute or regulations. Nor do the statute or regulations define "MSC Prime Contractor." The Manual lends further support to this view in clarifying that the MCS Contractor is responsible for all TRICARE Prime, Extra, *and* Standard claims. (*See* J.A. at 1006)

[21]**

8 On appeal, Defendant argues "there is no question that the parties can contractually eliminate the entitlement to Capital Reimbursement." (Def.'s Br. at 28-29) We agree. Yet, while this may be true, Defendant does not identify any provision in the Agreement to this effect and, accordingly, the argument does little to advance Defendant's cause.

This reading of the regulations is reinforced by the Department of Defense's ("DOD's") intent in implementing the TRICARE program. In response to its Proposed Rule, DOD received comments suggesting that the Final Rule should more specifically detail special reimbursement methods for network providers under *§ 199.17(p)*. DOD responded:

> The rule provides added flexibility to vary payment provisions from those established by regulation, to accommodate local market conditions. To attempt to specify in advance the possible reimbursement approaches would defeat our purpose of providing a flexible mechanism. We also disagree that network rate setting should be the same as under standard CHAMPUS rules; a key aim of managed care programs is to negotiate **[**22]** lower rates of reimbursement with networks of preferred providers.

TRICARE Program; Uniform HMO Benefit; Special Health Care Delivery Programs, 60 Fed. Reg. 52,078-01, at 52,086 (Oct. 5, 1995) (now codified at *32 C.F.R. § 199.17*). Although the parties here did not negotiate lower rates of reimbursement for the stop loss claims, Defendant did have increased flexibility in negotiations enabling it to insure access to health care for the TRICARE beneficiaries in its region.

We additionally note that this result is manifestly consistent in purpose and effect with more [HN8] traditional CHAMPUS reimbursement methods, which permit payment of capital costs along with additional payments for outlier cases. *32 C.F.R. § 199.14(a)(1)*. Specifically, the regulations provide reimbursement greater than the standard DRG-rate for cost outliers and for length-of-stay outliers. *Id.* at *§ 199.14(a)(1)(iii)(E)(1)(ii)* (providing additional payment for "[a]ny discharge which has standardized costs that exceed a[n established] threshold"); *id.* at *§ 199.14(a)(1)(iii)(E)(1)(i)* (additional payment for "[a]ny discharge . . . which **[**23]** has a length-of-stay (LOS) exceeding a threshold established"). The additional outlier payment in no way diminishes the provider's entitlement to capital payments under the same regulatory provision. *Id.* at *§ 199.14(a)(1)(iii)(G)*. Thus, Plaintiffs' receipt of both capital payments and inpatient reimbursement under the stop loss provisions runs consistent with the apparent intent of the regulators to appropriately reimburse more costly patient care.

Other portions of the TRICARE / CHAMPUS regulations demonstrate the DOD did not intend to preclude capital payments to providers under special **[*347]** programs, even though they may be reimbursed in excess of government allowable rates. For example, under the Supplemental Care Program, a program related to CHAMPUS, the military provides payment for health care services rendered at civilian facilities for its active duty members. *See 32 C.F.R. § 199.16(a)(2)*. [HN9] The regulations implementing the Supplemental Care Program acknowledge that the CHAMPUS provider reimbursement regulations generally will guide payment and administration of Supplemental Care claims. *32 C.F.R. § 199.16(c)*. However, **[**24]** the regulations further establish exceptions and clarifications to the general rule. *See 32 C.F.R. § 199.16(d)*. Specifically, the regulations clarify that "annual cost pass-throughs for capital . . . costs that are available under the CHAMPUS DRG-based payment system are also available, upon request, under the supplemental care program." *32 C.F.R. § 199.16(d)(4)*. Notwithstanding the entitlement to capital payments, that same subsection goes on to clarify that for some providers, "payment in excess of CHAMPUS allowable amounts" may be authorized. *Id.* at *§ 199.16(d)(5)*. Accordingly, the Supplemental Care Program regulations demonstrate that DOD contemplated simultaneous entitlement to capital payments and payments exceeding typical CHAMPUS allowable amounts.

In view of the foregoing, we [HN10] hold that the regulations authorize capital payments to TRICARE preferred network providers regardless of the methodology employed to reimburse claims for inpatient care -- whether it be the DRG-based system, or some alternative.

We next examine the significance, if any, of the capital payment certifications. Because the regulations authorize **[**25]** capital payments for all TRICARE / CHAMPUS providers, we find the certifications do not somehow operate to make Plaintiffs' application for and receipt of capital payments dispositive. Defendant would rely on Plaintiffs' capital payment certifications as evidence of mutuality of assent to modify the Agreement. To that end, Defendant seizes upon language contained on the capital payment certification forms and in correspondence between Plaintiffs and Defendant's government benefits administrator. The certification forms refer to TRICARE / CHAMPUS inpatient days as "[p]rovided in units subject to DRG-based payment," while the cor-

respondence characterizes capital payments as "reimbursement . . . under the CHAMPUS DRG-based payment system." (*See, e.g.*, J.A. at 1294, 1299)

Looking first to the plain language of the regulations, we find that Plaintiffs' hospitals were "subject to the DRG-based payment system." The CHAMPUS regulations provide --

> [HN11] (ii) Applicability of the DRG system.
>
> . . .
>
> (B) Services subject to the DRG-based payment system. All normally covered inpatient hospital services furnished to CHAMPUS beneficiaries by hospitals are subject to the CHAMPUS DRG-based **[**26]** payment system.
>
> . . .
>
> (D) Hospitals subject to the CHAMPUS DRG-based payment system. *All hospitals within the fifty states . . . which are certified to provide services to CHAMPUS beneficiaries are subject to the DRG-based payment system* except for . . . hospitals units which are exempt.

32 C.F.R. § 199.14(a)(1)(ii)(D) (emphasis added). [HN12] Typically, only hospital units exempt from the Medicare Prospective Payment **[*348]** System are exempt from the CHAMPUS DRG-based payment system. *Id.* at *§ 199.14(a)(1)(ii)(D)(1)-(5)*. Additionally, "[a]11 hospitals subject to the CHAMPUS DRG-based payment system . . . may be reimbursed for allowed capital . . . costs by submitting a request to the CHAMPUS contractor." *Id.* at *§ 199.14(a)(1)(iii)(G)(3)*.

[HN13] The capital payment provision of the CHAMPUS regulations lists the information required in order to verify the appropriate capital payment amount. Among this list, the regulation directs providers to submit "[t]otal inpatient days provided to all patients in *units subject to DRG-based payment* " and "[t]otal allowed CHAMPUS inpatient days provided in *units subject to DRG-based payment*." *Id* **[**27]** . at *§ 199.14(a)(1)(iii)(G)(3)(vi)-(vii)* (emphasis added). The regulations notably do not define "DRG-based payment." Nor do the regulations clarify whether "DRG-based payment" in the former context refers collectively to Medicare and CHAMPUS inpatients, to some broader group, or to CHAMPUS alone. [9]

> 9 As the regulation provides,[HN14] "All costs reported to the CHAMPUS contractor must correspond to the costs reported on the hospital's Medicare cost report." *32 C.F.R. § 199.14(a)(1)(iii)(G)(3)*. The term "DRG-rate" originated in Medicare. *See id.* at *§ 199.14(a)(1)(i)(A)*.

The Manual makes clear, however, that TRICARE uses the certification forms to insure that it does not pay capital costs for patients whose other (primary) health insurance fully covered the patient's charges. TRICARE / CHAMPUS Policy Manual, 6010.53-M, Ch. 6, Section 8 at III.B.3 (*available at* J.A. at 1053) (setting forth the method of calculating capital payment and noting "[t]hroughout these calculations claims **[**28]** on which TRICARE / CHAMPUS made no payment because other health insurance paid the full TRICARE / CHAMPUS-allowable amount are not to be counted"). The Manual details the steps that providers must follow in determining the "total allowable TRICARE / CHAMPUS capital payment for DRG discharges." *Id.* To begin, providers calculate the total TRICARE / CHAMPUS inpatient days. According to the Manual, providers should exclude --

> (1) Any days determined to be not medically necessary, and
>
> (2) Days included on claims for which TRICARE / CHAMPUS made no payment because *other health insurance paid the full TRICARE / CHAMPUS-allowable amount.*

Id. (emphasis added). Later in the same section, the Manual clarifies that TRICARE will not make capital payments for claims of dual-eligible beneficiaries that were paid by Medicare. *Id.* at B.4.f (*available at* J.A. at 1058) Rather, it expressly states that "TRICARE capital . . . cost payments will be made only on claims on which TRICARE is the primary payer." *Id.* Thus, the point of the certification forms is to separate the claims for which TRICARE / CHAMPUS serves as the primary payor from those where third **[**29]** parties foot the bill.

As careful review of the regulations makes abundantly clear, [HN15] the CHAMPUS regulations were never thoroughly amended following implementation of the TRICARE program to allow for the possibility that MCS contractors would enter into alternative payment arrangements with health care providers in their networks. In fact, the DOD Final Rule implementing the TRICARE program proves as much. *TRICARE Program; Uniform HMO Benefit; Special Health Care Delivery Programs, 60 Fed. Reg. 52,078*-01, at 52,079 (Oct. 5, 1995) (now codified at *32 C.F.R. § 199.17*) ("Our regulatory approach is to **[*349]** leave the existing

CHAMPUS rules largely intact and to create new *sections 199.17* and *199.18* to describe the TRICARE Program and the uniform HMO benefit."). As a result, the claims forms and the capital payment request forms that the TRICARE / CHAMPUS regulations require TRICARE providers to use essentially pound a square peg to a round hole. They simply do not neatly fit together.

Furthermore, as a strictly factual matter, Defendant's proffered capital payment evidence does not "tend[] to make the existence of any fact that is of consequence to the **[**30]** determination of the action more probable than it would be" otherwise. *See Fed. R. Evid. 401*. Importantly, the Agreement at issue remained in effect from August 6, 1996 to May 6, 2001. Accordingly, only Plaintiffs' certifications for purposes of capital payment during Fiscal Years (FY) 1997 through 2001 would even *arguably* be relevant. In Plaintiffs' FY 1997 submission, they certified 536 "[t]otal inpatient days . . . [b]ased on discharges within [the] reporting period." (J.A. at 1284) From FY1998-2000, when TRICARE modified the certification form to request "[t]otal TRICARE/CHAMPUS inpatient days. . . [p]rovided in units subject to DRG-based payment," Plaintiffs' certification forms did not set forth a number. (J.A. at 1299, 1343, 1378) Rather, on each occasion, Plaintiffs directed the government benefits administrator to "Use System Data." (*Id.* In FY 2001, Plaintiffs failed to timely submit certification for capital payments. Thus, none of Plaintiffs' requests for capital payments during the relevant period affirmatively certified that the stop loss claims were "subject to DRG-based payment;" rather, Defendant's own government **[**31]** benefits administrator put forth the numbers that included Plaintiffs' stop loss inpatients. It strikes this Court as disingenuous that Defendant now seeks to rely on those certifications to establish mutuality of assent to modification of the Agreement, and communication of intent to waive its rights under the stop loss provisions. This is particularly so because evidence pre-dating and post- dating the relevant period clearly demonstrates that Plaintiffs applied for and received capital payments at times not covered by the Agreement.

Whether viewed as a legal conclusion or an evidentiary ruling, we affirm the district court's view on the significance of capital payment evidence.

II. ADDITIONAL CLAIMS ON APPEAL

On appeal, Defendant challenges several of the district court's conclusions of law, alleging: (1) Plaintiffs' application for and acceptance of capital payments effectively modified the contract such that the stop loss claims would be subject to the DRG-based payment system; (2) Plaintiffs waived their rights to payment under the stop loss provision and "decisively communicated . . . intent to waive" by certifying, for purposes of capital payment, that those "claims **[**32]** were subject to DRG-based payment," (Def.'s Br. at 38). Additionally, Defendant asserted defenses of equitable estoppel, failure to mitigate, and laches. [10] Finally, Defendant claims the district court abused its discretion in awarding prejudgment interest.

10 Although Defendant's "Statement of Issues" contemplates additional challenges to the district court's rulings, as we later note, Defendant waived them on appeal.

A. No Valid Modification Occurred

Defendant posits that Plaintiffs' application for and acceptance of capital payments effectively modified the contract. In Defendant's view, Plaintiffs demonstratively **[*350]** assented to modify the Agreement by certifying that the inpatient stop loss claims were "subject to the DRG-based payment system." Moreover, Defendant contends that the capital payments themselves constitute consideration. The district court concluded that "[t]he evidence did not reveal a meeting of the minds or an exchange of consideration necessary to support defendant's claim of **[**33]** modification." *Baptist Physician II, 415 F. Supp. 2d at 851.*[HN16] We review the district court's conclusions of law *de novo*. *See Kalamazoo River Study Group, 355 F.3d at 589*. In doing so, we uphold the district court's determination that the parties did not validly modify the Agreement.

Tennessee substantive law controls in the instant case, as it comes before us on diversity. [HN17] In Tennessee, the parties to an existing contract can modify its terms at any time. *Bonastia v. Berman Bros., Inc., 914 F. Supp. 1533, 1538 (W.D. Tenn. 1995)*. However, an existing contract cannot be unilaterally modified. *Balderacchi v. Ruth, 36 Tenn. App. 421, 256 S.W.2d 390, 391 (Tenn. Ct. App. 1952)*. Rather, valid modification requires "the same mutuality of assent and meeting of the minds as required to make a contract" in the first instance. *Id.*; *see also Prudential Secs. v. Mills, 944 F. Supp. 631, 635 (W.D. Tenn. 1996)*. Additionally, consideration must be exchanged to effect modification of an existing contract. *Boyd v. McCarty, 142 Tenn. 670, 222 S.W. 528, 529-30 (Tenn. 1920)*. Importantly for **[**34]** our purpose today though, "[p]erforming what was already promised in the original contract is not consideration to support a second contract." *Dunlop Tire & Rubber Corp. v. Serv. Merch. Co., 667 S.W.2d 754, 758-59 (Tenn. Ct. App. 1983)* (citing *Am. Fruit Growers, Inc. v. Hawkinson, 21 Tenn. App. 127, 106 S.W.2d 564 (Tenn. Ct. App. 1937))*.

To show mutual assent, Defendant relies on the certifications Plaintiffs submitted requesting capital payments. We cannot agree that the certifications manifest Plaintiffs' intent to modify the Agreement and forego

payment under the stop loss provisions therein contained. As previously discussed at length, neither the statute, nor the implementing regulations, nor the policy manual preclude Plaintiffs, as preferred network providers, from requesting and receiving capital payments. This is so notwithstanding the operation of an Agreement establishing a negotiated rate of reimbursement for inpatient care which exceeds 100% of the DRG-rate. Although Defendant, and other MCS Contractors, can expressly provide that negotiated rates include costs otherwise additionally payable under the statute and regulations, such as **[**35]** capital costs, providers remain eligible to receive such additional payments upon request. *See* TRICARE / CHAMPUS Policy Manual, 6010.53-M, Ch. 6, Section 8 at III.B.4.d. (*available at* J.A. 1057-58).

Defendant analogizes the instant case to *Bonastia*. There, a company hired the plaintiff as an account manager and by letter conveyed that plaintiff's "annual salary will be $ 62,400 for the next two years." *Bonastia, 914 F. Supp. at 1535*. On his first day of work, the plaintiff signed a document acknowledging that he "read and received the company's Employee Handbook and agrees to abide by the policies, procedures, and rules it contains." *Id.* The document continues, however, and clarifies that the "Employee Handbook is not, and is not intended to be, a contract of employment," and that the plaintiff's "employment is 'at will.'" *Id.* Nearly a year later, the plaintiff signed yet another copy of the acknowledgment form. *Id.* Less than two years after reporting to work, the company terminated the plaintiff, who then **[*351]** sued for breach of an employment contract. *Id. at 1535-36*. The court in *Bonastia* assumed that the company's letter **[**36]** constituted a binding two-year employment contract, but found the second acknowledgment form modified that contract to create an employment at-will arrangement. *Id. at 1538-39*.

Bonastia is not on point. Defendant likens Plaintiffs' capital payment certifications to the acknowledgment form in *Bonastia*. The acknowledgment form indicates an agreement to comply with the policies and procedures of the Employee Handbook. The capital payment certifications, however, do not reference the regulations, policies, or procedures governing TRICARE / CHAMPUS and, even if they did, those regulations and policies comprise a complex federal regulatory scheme devoid of a definition of "DRG-based payment." Ambiguously, the phrase "units subject to DRG-based payment" appears at two places in the certification forms -- both under "inpatient days" and under "total TRICARE/CHAMPUS inpatient days." (*See* J.A. at 1343) What is more, the information certified must comport with information submitted in the hospital's Medicare cost report and "DRG-based payment" is a phrase with its origins under the Medicare program. Thus, unlike the rather straightforward acknowledgment form in **[**37]** *Bonastia*, the signature of which could appropriately be taken to manifest intent, Plaintiffs' certifications for capital payment in the case at hand cannot be employed to demonstrate Plaintiffs' intent.

At any rate, Defendant cannot show valid consideration. The Agreement did not strip Plaintiffs of their entitlement to capital payment, even for the stop loss claims. In making capital payments to Plaintiffs, Defendant's government benefits administrator merely performed consistently with a pre-existing duty under the Agreement and the applicable regulations. *See Dunlop Tire & Rubber Corp., 667 S.W.2d at 758-59*. Additionally, under the TRICARE / CHAMPUS regulations and policies, Defendant's government benefits administrator made capital payments *independently* of Plaintiffs' regularly submitted claims for reimbursement under the Agreement. These constitute "pass-through" payments and, accordingly, although Plaintiffs submitted their capital payment requests to Defendant's government benefits administrator, the payments themselves flow directly from the federal government. *See* [HN18] *32 C.F.R. § 199.14(a)(1)(iii)(G)(3)* (" *CHAMPUS shall* **[**38]** *reimburse* the hospital its share of actual capital costs.")

(emphasis added); *see also* General Accounting Office, Defense Health Program (DHP), B-287619, (July 5, 2001), http://redbook.gao.gov/17/fl0083859.php ([HN19] "For payment of pass through costs, the contractor provides information to DOD to seek approval for payment. If DOD approves payment, the contractor is notified to pay the claim."). Thus, Defendant's claim of modification falls on two swords. We affirm the district court on this claim.

B. Plaintiffs Never Waived Their Rights

Defendant asserts that Plaintiffs waived their right to receive stop loss payments. To support this claim, Defendant states that, in early 1999, Plaintiffs knew of the stop loss underpayment and of Defendant's actions in capping those claims at 100% of the DRG-rate and, yet, did not terminate the Agreement. Defendant further relies on Plaintiffs' capital payment certifications as evidence of intent to waive. In fact, on more than one occasion, Defendant goes so far as to classify Plaintiffs' submission of capital payment requests as "unequivocal and decisive acts." **[*352]** (Def.'s Br. at 35, 37) The district court concluded, as a matter of law, that **[**39]** Plaintiffs did not "intentionally and knowingly waive[] their rights to receive payments pursuant to the stop loss provisions," nor did Plaintiffs "manifest any such intent." *Baptist Physician II, 415 F. Supp. 2d at 851*. Reviewing this issue *de novo*, *see Kalamazoo River Study Group, 355 F.3d at 589*, we agree with the district court that

Plaintiffs did not waive their right to payment under the stop loss provisions.

[HN20] Waiver is the knowing and intentional relinquishment or abandonment of a known right. *Gitter v. Tenn. Farmers Mut. Ins. Co., 60 Tenn. App. 698, 450 S.W.2d 780, 784 (Tenn. Ct. App. 1969)*; *Faught v. Estate of Faught, 730 S.W.2d 323, 325 (Tenn. 1987)*. There can, therefore, be no effective waiver of rights where a party either does not know its rights or fails to fully understand those rights. *Faught, 730 S.W.2d at 326*. Put another way, intent to waive is required. "Waiver may be proved by express declaration; or by acts and declarations manifesting an intent and purpose not to claim the supposed advantage; or by a course of acts and conduct." *Reed v. Wash. County Bd. of Educ., 756 S.W.2d 250, 255 (Tenn. 1988)*; **[**40]** *see also Faught, 730 S.W.2d. at 326*; *Gitter, 450 S.W.2d at 784*. Where a party seeks to prove waiver by course of conduct, "there must be clear, unequivocal and decisive acts of the party or an act which shows determination not to have the benefit intended in order to constitute a waiver." *Gitter, 450 S.W.2d at 784* (citing *Webb v. Bd. of Trs. of Webb Sch., 38 Tenn. App. 173, 271 S.W.2d 6, 19 (1954))*.

Plaintiffs did not knowingly relinquish their rights to reimbursement. At the time Plaintiffs entered into the Agreement, Plaintiffs lacked the resources necessary to adequately monitor third party payor compliance with agreed-upon contract terms and, thus, to identify underpayments. To more closely track payments, Plaintiffs acquired new payment tracking software (PCMS) and hired a contract analyst whose primary task was to monitor payments. Plaintiffs loaded their contract with Defendant into the PCMS system in November 1998 and, in early 1999, Plaintiffs learned -- through Hodge, its contract analyst -- that Defendant had been reimbursing stop loss claims at an amount lower than the stop loss amounts.

Plaintiffs' contract **[**41]** analyst began conversations with Defendant in February 1999 to secure full payment of the stop loss claims. On July 22, 1999, she wrote to Defendant's government benefits administrator demanding full payment of the stop loss claims. Plaintiffs never communicated an intent to waive Plaintiffs' rights under the Agreement, nor did Plaintiffs intend to waive those rights. By letter dated February 5, 2001, Defendant ultimately terminated the Agreement with Plaintiffs because they had reached an impasse on the amount due under the stop loss provisions. Additionally, Plaintiffs' request and receipt of capital payments cannot be deemed "clear, unequivocal and decisive acts . . . which show[] determination not to have the benefit intended." *See Gitter, 450 S.W.2d at 784*. Our exploration of the regulatory scheme underlying the TRICARE / CHAMPUS program proves as much. Consequently, we find that Plaintiffs did not waive their rights under the Agreement. [11]

11 Although Defendant's brief on appeal alludes to implied waiver, Defendant wholly fails to develop such an argument. Accordingly, Defendant has waived a challenge on implied waiver grounds. *See Moore v. LaFayette Life Ins. Co., 458 F.3d 416, 448 (6th Cir. 2006)* ([HN21] "The courts of appeals are not self-directed boards of legal inquiry and research, but essentially arbiters of legal questions presented and argued by the parties."); *Indeck Energy Servs. v. Consumers Energy Co., 250 F.3d 972, 979 (6th Cir. 2000)* ("[I]ssues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.").

[42] [*353] C. Laches Does Not Bar Plaintiffs' Claim, Nor Did Plaintiffs Fail to Mitigate**

The district court concluded that the doctrine of laches did not bar Plaintiffs' claim since Plaintiffs took action to obtain full reimbursement upon learning of the underpayment and filed suit "when [it] felt it had exhausted all options of receiving payment." *Baptist Physician II, 415 F. Supp. 2d at 852*. Additionally, the district court determined that, after learning of the breach, Plaintiffs did not fail to mitigate damages. Defendant challenges these conclusions. Again, we review *de novo*, *see Kalamazoo River Study Group, 355 F.3d at 589*, and Defendant's claims fail.

[HN22] "[E]quitable defenses may bar purely legal claims." *M.J. Jansen v. Clayton, 816 S.W.2d 49, 52 (Tenn. Ct. App. 1991)*. To successfully invoke the doctrine of laches, a defendant must show "an inexcusably long delay in commencing the action which causes prejudice to the other party," and mere delay will not suffice. *Patton v. Bearden, 8 F.3d 343, 347 (6th Cir. 1993)* (internal citations omitted); *see also M.J. Jansen, 816 S.W.2d at 51*. A finding **[**43]** of sufficient prejudice frequently follows from "the death of witnesses[,] . . . the loss of evidence," *M.J. Jansen, 816 S.W.2d at 52* (collecting cases), or "failure of memory resulting in obscuration of facts" which "render uncertain the ascertainment of truth, and make it impossible for the court to pronounce a decree with confidence." *Brown v. Ogle, 46 S.W.3d 721, 727 (Tenn. Ct. App. 2000)*.

Laches does not bar Plaintiffs' claim. Plaintiffs timely filed this suit within the applicable statute of limitations. *See Tenn. Code Ann. § 28-3-109* (six-year statute of limitations). Moreover, Plaintiffs filed suit in December 2001 -- ten months after Defendant notified Plaintiffs of its intent to terminate the Agreement following impasse, seven months after the effective termination date,

and approximately two years and ten months following discovery of the underpayments. Up until February 1999, Plaintiffs did not know that Defendant was reimbursing its stop loss claims at below the agreed-upon rate. At that time, Plaintiffs' contract analyst began conversations with Defendant to secure full payment of the stop loss claims. **[**44]** On July 22, 1999, the analyst wrote to Defendant's claims administrator demanding full payment of the stop loss claims. This delay does not rise to the level of "inexcusably long." Further, Defendant has not shown that it suffered prejudice in the form of lost evidence, deceased witnesses, or failed memory sufficient to impede the truth-finding process. See *M.J. Jansen, 816 S.W.2d at 52*; *Brown, 46 S.W.3d at 727*.

Neither can Defendant succeed on its claim of failure to mitigate. [HN23] The party alleging breach of contract "has a legal duty to exercise reasonable and ordinary care under the[] circumstances to prevent and diminish the damages." *ACG, Inc. v. Se. Elevator, Inc., 912 S.W.2d 163, 169 (Tenn. Ct. App. 1995)*. Although the injured party must take "reasonable and ordinary" steps to mitigate, "[o]ne is not required . . . to make extraordinary efforts." *Id.* (citing *Arkansas River Packet Co. v. Hobbs, 105 Tenn. 29, 58 S.W. 278, 282 (Tenn. 1900))*. Plaintiffs acted with "reasonable and ordinary care" by informing **[*354]** Defendant promptly upon discovery that, in their view, Defendant was in breach of the Agreement's stop **[**45]** loss provisions. Plaintiffs pressed their view in a subsequent letter and phone call with Defendant. Defendant concedes in its brief that it terminated the Agreement with Plaintiffs in February 2001 "because [Plaintiffs] insisted on being paid the full stop loss, and in excess of DRG." (Def.'s Br. at 21) Defendant knew of this insistence long before February 2001. Plaintiffs were not required "to make extraordinary efforts" to further clarify their position for Defendant's benefit. *See ACG, Inc., 912 S.W.2d at 169*. Consequently, we find that the district court correctly ruled that the defense of laches does not bar Plaintiffs' claim, and that Plaintiffs took reasonable steps to mitigate.

D. Prejudgment Interest

Defendant further argues that the district court abused its discretion in awarding prejudgment interest because "[u]p to the day of trial the number and amount of stop loss claims was contested." (Def.'s Br. at 46) The district court awarded prejudgment interest at a rate of ten percent per annum "from the date that payment was actually posted on each inpatient claim" improperly reimbursed. *Baptist Physician II, 415 F. Supp. 2d at 853.* **[**46]** In so doing, the district court observed that Plaintiffs "ha[d] remained without the use of the money" and "[Defendant] could have entirely avoided the dispute . . . had it simply disclosed to [Plaintiffs] prior to signing the Agreement that it had no intention of paying more than CHAMPUS DRG on those claims." *Id.* [HN24] On review, challenges to the district court's award of prejudgment interest "will not be disturbed . . . unless the record reveals a manifest and palpable abuse of discretion." *Myint v. Allstate Ins. Co., 970 S.W.2d 920, 927 (Tenn. 1998)*; *see also Daily v. Gusto Records, Inc., 14 F. App'x 579, 591 (6th Cir. 2001)* (noting that state law determines the appropriate standard of review). We find no abuse of discretion.

[HN25] Where consistent with principles of justice and equity, Tennessee Code provides for the award of prejudgment interest at a rate not to exceed ten percent per annum. *Tenn. Code Ann. § 47-14-123*. First and foremost, principles of equity guide trial courts in exercising their discretion to award prejudgment interest. *Myint, 970 S.W.2d at 927*; *see also Otis v. Cambridge Mut. Fire Ins. Co., 850 S.W.2d 439, 447 (Tenn. 1992)*. **[**47]** Second, a trial court will more readily award prejudgment interest "when the amount of the obligation is certain, or can be ascertained by proper accounting." *Myint, 970 S.W.2d at 927* (citing *Mitchell v. Mitchell, 876 S.W.2d 830, 832 (Tenn. 1994))*. Third, "interest is allowed when the existence of the obligation itself is not disputed on reasonable grounds." *Id.* While useful as guideposts, the Tennessee Supreme Court has observed that "these criteria have not been used to deny prejudgment interest in every case where the defendant reasonably disputed the existence or amount of an obligation." *Id.*

The district court did not abuse its discretion in awarding prejudgment interest. First, the award is consistent with principles of equity. Defendant entered into the Agreement knowing full well it had no intention of ever paying over 100% of the CHAMPUS DRG-rate on the stop loss claims. Defendant deliberately failed to reimburse Plaintiffs according to the stop loss provisions, and thereby deprived Plaintiffs of the use of the difference in reimbursement. Second, the parties stipulated to the "accuracy, and admissibility" of a list detailing the **[**48]** inpatient claims at issue in the case. (J.A. at 1568, 1570-74) **[*355]** Thus, the amount of the obligation could be readily "ascertained by proper accounting." *See Myint, 970 S.W.2d at 927*. Finally, although Defendant disputed Plaintiffs' claim of breach, it did not "reasonably dispute" the claim in light of its intent from the start of the Agreement *not* to honor the stop loss reimbursement provisions contained therein. Accordingly, we find the district court did not abuse its discretion in awarding prejudgment interest.

E. Claims Waived on Appeal

At the outset, Defendant's brief contemplates challenges to the district court's conclusions on Defendant's

equitable estoppel claim and its counterclaim. However, Defendant's brief is notably devoid of any developed argumentation on these issues. Accordingly, Defendant has waived these challenges. *See Moore, 458 F.3d at 448*; *Indeck Energy Servs., 250 F.3d at 979*.

CONCLUSION

For the foregoing reasons, we **AFFIRM** the district court's order.

EXHIBIT "C"

LEXSEE 2004 U.S. DIST. LEXIS 22147

BOARD OF TRUSTEES OF BAY MEDICAL CENTER, a special district of the state of Florida; BAPTIST HOSPITAL, INC., a Florida not for profit corporation; and THE HEALTHCARE AUTHORITY OF THE CITY OF HUNTSVILLE, an Alabama public corporation, on their own behalf and on behalf of all CLASS MEMBERS similarly situated, Plaintiffs, v. HUMANA MILITARY HEALTHCARE SERVICES, INC., a Delaware corporation; OFFICE OF CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES and TRICARE MANAGEMENT ACTIVITY, subdivisions of the DEPARTMENT OF DEFENSE OF THE UNITED STATES OF AMERICA; and DONALD RUMSFELD, in his official capacity as the Secretary of Defense for the United States of America, Defendants.

Case No. 5:03-cv-144/MCR

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF FLORIDA, PANAMA CITY DIVISION

2004 U.S. Dist. LEXIS 22147

March 16, 2004, Decided

SUBSEQUENT HISTORY: Remanded by *Bd. of Trs. of Bay Med. Ctr. v. Humana Military Healthcare Servs., 2005 U.S. App. LEXIS 1399 (Fed. Cir., Jan. 28, 2005)*

DISPOSITION: [*1] Defendant Humana Military Healthcare Services' motion to dismiss plaintiffs' complaint, or in alternative, to transfer denied. Defendants Tricare Management Activity and Donald Rumsfeld's motion to dismiss, or alternatively, to stay claim for declaratory judgment granted. Count II of complaint dismissed without prejudice. Stay in this case lifted.

LexisNexis(R) Headnotes

Civil Procedure > Jurisdiction > Subject Matter Jurisdiction > Jurisdiction Over Actions > General Overview
Civil Procedure > Pleading & Practice > Defenses, Demurrers, & Objections > Failures to State Claims
Civil Procedure > Pleading & Practice > Defenses, Demurrers, & Objections > Motions to Dismiss

[HN1] Challenges to subject matter jurisdiction under *Fed. R. Civ. P. 12(b)(1)* come in two forms, facial and factual challenges. Facial challenges are limited to the four corners of the complaint while factual challenges permit investigation of matters outside the pleadings themselves. Facial attacks on the complaint require a court merely to look and see if the plaintiff has sufficiently alleged a basis of subject matter jurisdiction, and the allegations in his complaint are taken as true for the purposes of the motion. A facial attack affords a plaintiff safeguards similar to those provided in a *Fed. R. Civ. P. 12(b)(6)* motion. If the jurisdictional allegations in the complaint are sufficient, the complaint stands. Factual attacks, on the other hand, challenge the existence of subject matter jurisdiction in fact, irrespective of the pleadings, and matters outside the pleadings, such a testimony and affidavits, are considered.

Civil Procedure > Jurisdiction > General Overview
Civil Procedure > Pleading & Practice > Defenses, Demurrers, & Objections > Motions to Dismiss
Civil Procedure > Summary Judgment > General Overview

[HN2] When the facts of a case do not implicate the merit's of a plaintiff's case, a trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case. In short, no presumptive truthfulness attaches to a plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims. On the other hand, if an attack on subject matter jurisdiction implicates an element of a plaintiff's cause of action, then: The proper course of action for a district court is to find that jurisdiction exists and deal with the objection as a direct attack on the merits of the plaintiff's case. Judicial economy is best promoted when the existence of a federal right is directly reached, and where no

claim is found to exist, the case is dismissed on the merits. This refusal to treat indirect attacks on the merits as *Fed. R. Civ. P. 12(b)(1)* motions provides, moreover, a greater level of protection to the plaintiff who in truth is facing a challenge to the validity of his claim: the defendant is forced to proceed under *Fed. R. Civ. P. 12(b)(6)* or *Fed. R. Civ. P. 56* both of which place great restrictions on a district court's discretion.

Administrative Law > Sovereign Immunity
Civil Procedure > Jurisdiction > Subject Matter Jurisdiction > Jurisdiction Over Actions > Exclusive Jurisdiction
Governments > Courts > Authority to Adjudicate
[HN3] The Court of Federal Claims has exclusive jurisdiction over cases in which the federal government's potential liability exceeds $ 10,000. *28 U.S.C.S. §§ 1346(a)(2)* and *1491(a)(1)*

Civil Procedure > Jurisdiction > General Overview
Civil Procedure > Pleading & Practice > Service of Process > General Overview
Civil Procedure > Parties > Joinder > Necessary Parties
[HN4] See *Fed. R. Civ. P. 19(a)*.

Civil Procedure > Parties > Joinder > Necessary Parties
[HN5] *Fed. R. Civ. P. 19* provides a two step analytical framework to determine whether or not an action should proceed in a non-party's absence. The first question is whether complete relief can be afforded in the present procedural posture, or whether the non-party's absence will impede either the non-party's protection of an interest at stake or subject parties to a risk of inconsistent obligations. Only when the answer to that question is yes and the non-party cannot be joined does a court move on to step two. On step two, a court must determine whether "in equity and good conscience" the litigation should go forward without the non-party.

Contracts Law > Breach > Causes of Action > Elements of Claims
Contracts Law > Breach > Material Breach
[HN6] The elements of a breach of contract action are: (1) a valid contract; (2) a material breach; and (3) damages.

Administrative Law > Sovereign Immunity
Public Contracts Law > Bids & Formation > Subcontracts & Subcontractors > General Overview
Public Contracts Law > Dispute Resolution > Jurisdiction
[HN7] Where there is a contract between only private entities, a subcontractor is unable to sue the United States pursuant to that contract. Privity of contract with the United States is required in order to establish jurisdiction under the Tucker Act, *28 U.S.C.S. § 1491*.

Business & Corporate Law > Agency Relationships > General Overview
Governments > Federal Government > Claims By & Against
[HN8] To demonstrate an agency relationship, a subcontractor must show that: (1) prime contractor was acting as a purchasing agent for the government; (2) the agency relationship between the government and the prime contractor was established by clear contractual consent; and (3) the prime contractor stated that the government would be directly liable to the subcontractors for the purchase price. A contractor cannot bind the government via provisions of a subcontract unless such authority has been granted by the government. Courts look to the provisions of a prime contract to determine whether or not such consent exists.

Civil Procedure > Justiciability > Standing > General Overview
Civil Procedure > Jurisdiction > General Overview
Constitutional Law > The Judiciary > Case or Controversy > General Overview
[HN9] Standing is a threshold jurisdictional question which must be addressed prior to and independent of the merits of a party's claim. In order to satisfy the constitutional requirements of standing, a plaintiff must allege the following three things: (1) that he or she has suffered or will immediately suffer an injury; (2) that the injury is fairly traceable to the defendant's challenged actions; and (3) that a favorable court ruling is likely, as opposed to merely speculatively, to redress the plaintiff's injury. Satisfaction of this three-part test is required where a plaintiff seeks to challenge agency action pursuant to the Administrative Procedure Act, *5 U.S.C.S. § 701 et seq.*

Civil Procedure > Justiciability > Standing > General Overview
Constitutional Law > The Judiciary > Case or Controversy > Standing > General Overview
[HN10] In evaluating U.S. Const. art. III's causation, or "traceability, requirement, courts are concerned with something less than the concept of "proximate cause." As

the United States Court of Appeals for the Eleventh Circuit has noted, no authority even remotely suggests that proximate causation applies to the doctrine of standing. Instead, even harms that flow indirectly from the action in question can be said to be "fairly traceable" to that action for standing purposes. To prove standing a plaintiff must establish causation--a "fairly traceable" connection between the alleged injury in fact and the alleged conduct of the defendant.

Civil Procedure > Justiciability > Standing > General Overview
Constitutional Law > The Judiciary > Case or Controversy > Standing > General Overview
[HN11] To meet the redressability requirement for standing, plaintiffs must allege that a favorable court decision is likely to remedy plaintiffs' injury. In other words, it must be likely, not merely speculative, that plaintiffs' injury will be redressed by a favorable decision.

Civil Procedure > Justiciability > Case or Controversy Requirements > Adverse Legal Interests
Civil Procedure > Justiciability > Case or Controversy Requirements > Immediacy
Constitutional Law > The Judiciary > Case or Controversy > Advisory Opinions
[HN12] Under U.S. Const. art. III, the question in each case is whether the facts alleged, under all of the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Whether a controversy is sufficiently immediate or real is a question of degree that must be determined on a case-by-case basis.

COUNSEL: For BOARD OF TRUSTEES OF BAY MEDICAL CENTER, A SPECIAL DISTRICT OF THE STATE OF FLORIDA, BAPTIST HOSPITAL INC, A FLORIDA NOT FOR PROFIT CORPORATION, HEALTHCARE AUTHORITY OF THE CITY OF HUNTSVILLE, AN ALABAMA PUBLIC CORPORATION, Plaintiffs: JAMES NIXON DANIEL, RUSSELL FRANK VAN SICKLE, BEGGS & LANE, PENSACOLA, FL.

For HUMANA MILITARY HEALTHCARE SERVICES INC, Defendant: CHARLES MICHAEL TRIPPE, DAVID C REEVES, ROBERT BRUCE PARRISH, ROBERT E WARREN, MOSELEY WARREN PRICHARD ETC, JACKSONVILLE, FL; JOHN W MERTING, JOHN W MERTING PA, GULF BREEZE, FL; KIMBERLY H ISRAEL, HELD & ISRAEL, JACKSONVILLE, FL.

For OFFICE OF CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES, TRICARE MANAGEMENT ACTIVITY, DEPARTMENT OF DEFENSE, DONALD RUMSFELD, Defendants: JD ROY ATCHISON, US ATTORNEY, NORTHERN DISTRICT OF FLORIDA, PENSACOLA, FL; SARA W CLASH-DREXLER, US DEPARTMENT OF JUSTICE, WASHINGTON, DC.

JUDGES: M. CASEY RODGERS, United States District Judge.

OPINION BY: M. CASEY RODGERS

OPINION

ORDER

On June 6, 2003, Plaintiffs BAY MEDICAL CENTER, BAPTIST HOSPITAL, INC., and THE HEALTHCARE AUTHORITY **[*2]** OF THE CITY OF HUNTSVILLE (collectively referred to as "Plaintiffs") filed the current action in this Court based on both federal question and diversity jurisdiction, asserting two causes of action: (1) breach of contract against Defendant HUMANA MILITARY HEALTH SERVICES, INC. ("Humana"); and (2) declaratory judgment against Defendants TRICARE MANAGEMENT ACTIVITY and DONALD RUMSFELD ("Government"). (Doc. 1). On August 25, 2003, the Government filed a *Rule 12(b)(1)* motion to dismiss, or in the alternative, to stay the declaratory judgment claim (see doc. 16) along with a supporting memorandum of law (see doc. 17), which is now pending. On the same day, Humana also filed a *Rule 12(b)(1)* motion to dismiss, or in the alternative, to transfer venue to the Court of Federal Claims (see doc. 11) along with a supporting memorandum of law (see doc. 12), which is now also pending. [1] One month later, Plaintiffs (see doc. 29) and Humana (see doc. 27) each timely filed a response in opposition to the Government's motion. On the same day, Plaintiffs (see doc. 30) and the Government (see doc. 28) each filed a timely response in opposition to Humana's motion. [2] The **[*3]** Court heard oral arguments on both motions on January 9, 2004. (Docs. 66, 68). The Court now concludes that the Government's motion should be granted for lack of standing of the Plaintiffs and that Humana's motion should be denied because the Court does have subject matter jurisdiction over Plaintiffs' breach of contract claim.

1 On August 25, 2003, Humana also filed affidavits in support of its motion (see doc. 13), and one day later, filed additional supporting affidavits (see doc. 14).

2 On October 22, 2003, the Government filed a declaration in support of its response to Humana's motion. (Doc. 42).

Facts

The Department of Defense ("DOD"), pursuant to authority from Congress, established the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") in 1967. CHAMPUS beneficiaries include retired armed forces personnel and dependents of both active and retired military personnel. The DOD subsequently established TRICARE, a managed healthcare program which involves **[*4]** the competitive selection of contractors to financially underwrite the delivery of health care services under CHAMPUS. TRICARE Management Activity ("TMA"), which was previously known as Office of CHAMPUS, is the government office charged with the responsibility of administering TRICARE/CHAMPUS. TMA assists in the operational management and direction of all CHAMPUS programs and activities.

On January 23, 1996 (effective November 28, 1995), the DOD entered into a contract ("Prime Contract") with Humana whereby Humana agreed to provide comprehensive health care and associated services for all CHAMPUS beneficiaries residing in Regions 3 and 4 (Alabama, Florida, Georgia, Mississippi, South Carolina, a small area in Arkansas, a portion of eastern Louisiana, and most of Tennessee). Under the Prime Contract, Humana became a managed care support ("MCS") [3] contractor. The Prime Contract was based on a fixed price with monthly payments to Humana, which was "intended to create strong incentives for efficiency and cost-effectiveness in the delivery of health care services." (Doc. 1, P10). Under the Prime Contract, the contractor assumed the risk for the cost of healthcare provided to the **[*5]** CHAMPUS beneficiaries. The Prime Contract provides that "...if the contractor is able to control costs while providing the contractually required services, the contractor receives a larger profit. If the contractor is unable to control costs while providing the required services, the contractor loses its profit and a previously negotiated risk premium." (Doc. 42, P8).

3 Under an MCS contract, a contractor is required to: "[establish] and manage a network of health care providers; [enroll] beneficiaries in the TRICARE Prime (health maintenance organization option); operate a medical management program; [process] health care claims; provide customer services; educate [the] providers and beneficiaries regarding TRICARE programs and procedures; operate local TRICARE Service Centers; and provide government access to data." *Sierra Military Health Services, Inc. v. United States, 58 Fed. Cl. 573, 575 (Fed. Cl. 2003).*

The Prime Contract required Humana to establish "civilian provider networks" **[*6]** for those CHAMPUS beneficiaries residing within Regions 3 and 4. A "provider" is "an entity or person that provides healthcare." (Doc. 1, P11). [4] Humana established the civilian provider networks through contractual arrangements with the individual providers. Humana negotiated different payment amounts and methodologies with the providers in order to encourage them to participate in the network; however, the Prime Contract required Humana to "make timely and accurate reimbursement to all providers of care with whom it has contracts in strict accordance with the terms and conditions of the contracts." (Doc. 1, P12).

4 Hospitals are institutional providers, but physicians are professional (*i.e.,* non-institutional) providers.

Prior to TRICARE, the DOD used claims processors, called fiscal intermediaries, to process claims under the CHAMPUS program. Fiscal intermediaries were not legally responsible for claims that arose regarding the discharge of those duties required by the fiscal intermediary ("FI") **[*7]** contracts. When the FI contracts expired, the DOD began using MCS contracts, like the Prime Contract in the current case. Noticeably absent from the MCS contracts are indemnity provisions, which had been included in the FI contracts. Pursuant to the indemnity provision in the FI contracts, the Government agreed to hold the fiscal intermediaries harmless and indemnify them for any judgment, settlement, or costs arising out of the contractor's function as a fiscal intermediary. The FI contracts also explicitly stated that the Government was the real party in interest in civil lawsuits which sought the disbursement of funds, because the funds provided to the fiscal intermediaries with which to pay CHAMPUS claims were disbursed directly from the United States Treasury. When the DOD made the change to MCS contracts, it also made the decision to not include an indemnity provision in them. By using the MCS contracts, the DOD intended to create a new contractual relationship with the MCS contractor. [5]

5 In fact, pursuant to the MCS contracts, the MCS contractor is solely liable for negligent acts or omissions of contractor supplied resource support and resource sharing personnel.

[*8] Under the Prime Contract, TMA pays a monthly sum via electronic fund transfer to Humana based on several contract service categories, including healthcare costs and administrative costs. "The healthcare price is the cost to the government of certain specified health care services. The administrative price is the

cost to the government for all administrative functions required under the contract such as customer services and claims processing." (Doc. 42, P9). From the healthcare portion of the monthly payments, Humana is responsible for the payment of all healthcare benefits for the CHAMPUS beneficiaries residing in Regions 3 and 4 to the network providers based on the terms of Humana's network provider contracts.

The Prime Contract permits Humana to negotiate rates of payment with its network providers. Those rates of payment are subject to the maximum payment methodologies set forth by federal law. Federal law prohibits the reimbursement of out-patient *professional* services billed by institutional providers in excess of the CHAMPUS/TRICARE Maximum Allowable Charge ("CMAC"). "CMACs are the allowable amounts used by TMA to pay for professional[, *i.e.,* non-institutional, **[*9]**] providers that are either rendered on an in-patient or out-patient basis." (Id., P14). "Although the CMAC methodology limits the MCS contractor reimbursement from the government for institutional out-patient professional services, the [Prime Contract] between Humana and the government does allow the contractor to pay these providers (on an annual basis or by other arrangement) sums in addition to government imposed limits on individual claims...." (Id.). [6] "As stated in the [Prime Contract], it is TMA policy that these additional sums must come out of the funds the government pays to Humana for administrative services (not health care services).... That is, all additional sums paid to providers by Humana must come from contractor funds." (Id.). In other words, if Humana's negotiated rates exceeded the Government's reimbursement limits, then Humana would have to pay for the overage out of its profit. [7]

6 MCS contractors are allowed "to pay network providers sums in addition to individual claims payments if it is deemed necessary to entice providers into the network," but the contractor cannot use "health care dollars...to pay amounts in excess of the maximum payment methodology set forth by federal law...." (Doc. 66, Attach. Exh. 2; see also Id., Exh. 3).

[*10]

7 If, hypothetically, a MCS contractor breached one of its network provider contracts, the resulting damages would not be allowable healthcare costs. In addition, such damages could not be added to the administrative costs paid to the MCS contractor by the Government, because the administrative costs are fixed by the MCS contract and are not subject to adjustment. Thus, any monetary damages recovered by Plaintiffs would not be paid with funds directly from the federal treasury.

Plaintiffs are all institutional providers with whom Humana contracted to provide healthcare services to CHAMPUS beneficiaries within Regions 3 and 4. The network provider contracts [8] between Humana and Plaintiffs generally explain that, in exchange for providing certain "covered" healthcare services to the beneficiaries, Humana would pay Plaintiffs agreed upon amounts for those services as established by the contracts. One category of the healthcare services that Plaintiffs contracted to provide was outpatient non-surgical services.

8 The Government was not a party to those network provider contracts, and in fact, Plaintiffs have no direct relation ship with the Government.

[*11] On September 23, 1998, Dr. John E. Crum, MD, who was Humana's Chief Medical Officer, sent a letter to Beverly Carey, a TMA contracting officer, seeking advice as to the propriety of a proposed billing practice. Dr. Crum informed Ms. Carey that Humana "desired to apply the CMAC fee schedule, professional and technical components as appropriate, to reimburse hospitals for radiology, laboratory, other diagnostic, and medical services performed in the outpatient setting." (Doc. 13, Affidavit of Ray Prior, Exh. H). Dr. Crum inquired as to whether or not such a proposed billing practice would comply with TMA policy. On December 1, 1998, Ms. Carey responded to Dr. Crum's letter. She informed him that his proposal was "not inconsistent with TMA policy." (Id., Exh. I). However, she cautioned that TMA planned to adopt the Medicare reimbursement system but that an implementation of that system was a few years away. Ms. Carey told him to "please continue to operate under current guidelines" until the time such a system could be implemented. (Id.).

Prior to October 1, 1999, Humana paid Plaintiffs the agreed upon amounts according to the terms of the written contracts. Beginning **[*12]** October 1, 1999, however, Humana (without prior notice) ceased paying Plaintiffs the normal amount for the reimbursement of outpatient non-surgical services. Humana began reducing the payments to Plaintiffs by applying CMAC rates to those services. In Count I of the complaint, Plaintiffs assert that Humana's application of the CMAC rates to cap the reimbursement of out-patient non-surgical services breached the previously agreed-upon reimbursement methodology for those services. To be absolutely clear, when an outpatient non-surgical service is billed, there are two components to the bill, a professional and a technical component. Plaintiffs admit that the services complained-of in this case involve only Humana's reimbursement of the technical component of the bill for radiology and laboratory fees, *i.e.,* the fees charged by the institutional providers for use of radiological and laboratory equipment. Plaintiffs' breach of contract claim does

not involve professional charges of those physicians who were involved with the delivery of Plaintiffs' radiological or laboratorial services.

Plaintiffs allege that, on March 10, 2000, approximately five (5) months after Humana began **[*13]** reducing the payments to Plaintiffs, the TRICARE program issued a policy related to the reimbursement of outpatient hospital services. It is alleged that the policy approved of the application of CMAC rates to institutional providers. [9] In Count II of Plaintiffs' complaint, Plaintiffs assert that the policy is void for two reasons: (1) "it was in direct conflict with the reimbursement plan for those services promulgated as *32 C.F.R. § 199.14*[;]" and (2) "it was actually an attempt to issue a substantive rule that [should have been] promulgated as a regulation." (Id., P29). [10]

9 Plaintiffs quote a portion of the policy in their complaint; however, Plaintiffs did not provide the Court with a copy of the policy statement in its entirety. (Doc. 1, P27).

10 Plaintiffs also allege that "regardless of the validity of the policy, its existence did not change or otherwise affect the contracts entered into between Humana and plaintiffs and the members of the proposed class." (Doc. 1, P29).

Then **[*14]** on or after August 12, 2002, Plaintiffs allege that the DOD issued a regulation, *32 CFR 199.14(a)(5)(iv)*, as to the application of CMAC rates to institutional providers regarding radiology services. In Count II, Plaintiffs claim that the regulation is invalid for four reasons: (1) "the regulation requires that laboratory services are to be reimbursed under home health rules as set forth in *32 CFR 199.14(h)(1)(viii)(1998)*, which is in error[;]" (2) "the promulgation of [the] regulation was deficient because it failed to include the changes to the institutional outpatient reimbursement payments in the title or summary description of the interim final rule[;]" and (3) "the regulatory procedures section of the proposed interim rule refers to an analysis as to the proposed rule's effect on skilled nursing facilities, but no analysis as to the effect on the hospitals which would be affected by the reimbursement changes as to the outpatient procedures[;]" and (4) "the standard practice of soliciting public comments prior to issuance of the regulation was improperly not followed." (Id., P30). [11]

11 Plaintiffs also allege that "institutional providers are not subject to CMAC rates for outpatient non-surgical procedures and have not been subject to such rates at any time relevant to this litigation." (Doc. 1, P31). Furthermore, Plaintiffs claim that "CMAC rates are applicable only to individual non-institutional providers of services." (Id.).

[*15] ***Standard for a Motion to Dismiss Pursuant to Rule 12(b)(1)***

[HN1] Challenges to subject matter jurisdiction under *Rule 12(b)(1) of the Federal Rules of Civil Procedure* come in two forms, facial and factual challenges. See *Lawrence v. Dunbar, 919 F.2d 1525, 1528-29 (11th Cir. 1990)*. Facial challenges are limited to the four corners of the complaint while factual challenges permit investigation of matters outside the pleadings themselves. See *Garcia v. Copenhaver, Bell, and Assocs., 104 F.3d 1256, 1260-61 (11th Cir. 1997)*. "Facial attacks on the complaint [require] the court merely to look and see if [the] plaintiff has sufficiently alleged a basis of subject matter jurisdiction, and the allegations in his complaint are taken as true for the purposes of the motion." *Id., 919 F.2d at 1529 (11th Cir. 1990)* (quoting *Menchaca v. Chrysler Credit Corp., 613 F.2d 507, 511 (5th Cir.))* (internal quotations omitted). A facial attack affords a plaintiff safeguards similar to those provided in a *Rule 12(b)(6)* motion. See *Lawrence, 919 F.2d at 1529*. If the jurisdictional allegations in the complaint **[*16]** are sufficient, the complaint stands. See *Paterson v. Weinberger, 644 F.2d 521, 523 (5th Cir. 1981)*. "Factual attacks, on the other hand, challenge the existence of subject matter jurisdiction in fact, irrespective of the pleadings, and matters outside the pleadings, such a testimony and affidavits, are considered." Id. (quoting *Menchaca, 613 F.2d at 511*) (internal quotations omitted). In the instant case, the Court will treat Humana's motion as "factual" challenge and the Government's motion as a "facial" challenge. [12]

12 The Government asserts in its motion that it is raising purely a facial attack. Humana's motion does not specify whether it is facial or factual, but it does refer to matters outside of the pleadings. As a result, the Court will treat Humana's motion as a factual challenge to subject matter jurisdiction.

[HN2] When the facts of a case do not implicate the merit's of a plaintiff's case, "the trial court is free to weigh the evidence and satisfy itself as to **[*17]** the existence of its power to hear the case." *Lawrence, 919 F.2d at 1529* (citation omitted). "In short, no presumptive truthfulness attaches to [a] plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." Id. On the other hand, if the attack on subject matter jurisdiction implicates an element of a plaintiff's cause of action, then:

> The proper course of action for the district court...is to find that jurisdiction exists and deal with the objection as a direct attack on the merits of the plaintiff's case....Judicial economy is best promoted when the existence of a federal right is directly reached, and where no claim is found to exist, the case is dismissed on the merits. This refusal to treat indirect attacks on the merits as *Rule 12(b)(1)* motions provides, moreover, a greater level of protection to the plaintiff who in truth is facing a challenge to the validity of his claim: the defendant is forced to proceed under *Rule 12(b)(6)*...or *Rule 56*...both of which place great restrictions on the district court's discretion....

[*18] ***Garcia, 104 F.3d at 1261*** (quoting *Williamson v. Tucker, 645 F.2d 404, 415-16 (5th Cir. 1981)*, cert. denied, *454 U.S. 897, 102 S. Ct. 396, 70 L. Ed. 2d 212 (1981)).*

A. Humana's Motion to Dismiss

In its motion to dismiss, Humana argues that the Government is 100% liable for any breach of the network provider contracts by Humana. Humana maintains that the Government is the real party in interest, because Humana is essentially a fiscal intermediary who simply processes claims on behalf of the Government for the CHAMPUS/TRICARE program. Because Humana claims that the Government is the real party in interest, Humana asserts that the Government is an indispensable party as to Count I.

If the Government was in fact an indispensable party and solely liable for any breach of contract damages, this Court would lack subject matter jurisdiction over Count I. [HN3] The Court of Federal Claims has exclusive jurisdiction over cases in which the federal government's potential liability exceeds $ 10,000.00. See *28 U.S.C. §§ 1346(a)(2)* and *1491(a)(1) (West 2003)*. Because Humana's claim for damages in **[*19]** Count I would likely exceed $ 10,000.00, the only court that would have subject matter jurisdiction over Count I would be the Court of Federal Claims. Accordingly, Humana seeks dismissal of Count I, or as an alternative to dismissal, transfer of the case to the Court of Federal Claims pursuant to *28 U.S.C. § 1631*.

1. Indispensable Party Under Rule 19

Rule 19 of the Federal Rules of Civil Procedure provides, in pertinent part:

> [HN4] (a) Persons to be Joined if Feasible. A person who is subject to service of process and whose joinder will not deprive the court of jurisdiction over the subject matter of the action shall be joined as a party in the action if (1) in the person's absence complete relief cannot be accorded among those already parties, or (2) the person claims an interest relating to the subject of the action and is so situated that the disposition of the action in the person's absence may (i) as a practical matter impair or impede the person's ability to protect that interest or (ii) leave any of the persons already parties subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations by **[*20]** reason of the claimed interest. If the person has not been so joined, the court shall order that the person be made a party. If the person should join as a plaintiff but refuses to do so, the person may be made a defendant, or, in a proper case, an involuntary plaintiff. If the joined party objects to venue and joinder of that party would render the venue of the action improper, that party shall be dismissed from the action.

FED. R. CIV. P. 19(a) (2003). [HN5] *Rule 19* provides a two step analytical framework to determine whether or not an action should proceed in a non-party's absence. See *City of Marietta v. CSX Transp., Inc., 196 F.3d 1300, 1305 (11th Cir. 1999)*. "The first question is whether complete relief can be afforded in the present procedural posture, or whether the nonparty's absence will impede either the nonparty's protection of an interest at stake or subject parties to a risk of inconsistent obligations." *Id.* Only when the answer to that question is yes and the nonparty cannot be joined does the Court move on to step two. See *id.* (citing *Temple v. Synthes Corp., Ltd., 498 U.S. 5, 8, 111 S. Ct. 315, 316, 112 L. Ed. 2d 263 (1990))*. **[*21]** On step two, a court must determine whether "in equity and good conscience" the litigation should go forward without the non-party. See *id.* In this case, because the Court answers the first question in the negative, the Court will not reach step two.

Under the first step in the *Rule 19* analysis, the Court must determine whether complete relief can be afforded with the present parties, or whether the nonparty has an interest in the litigation. In order to make such a determination, the Court must first inquire into whether suit may be brought against the Government for

Humana's alleged breaches of the network provider contracts.

[HN6] The elements of a breach of contract action are: (1) a valid contract; (2) a material breach; and (3) damages. See *J.J. Gumberg Co. v. Janis Services, Inc., 847 So. 2d 1048, 1049 (Fla. 4th D.C.A. 2003)*. In the current case, the provider network contracts were valid contracts between only Plaintiffs and Humana. In other words, the Government was not a party to those contracts. Therefore, Plaintiffs have no privity of contract with the Government. See *Merritt v. United States, 267 U.S. 338, 340-41, 45 S. Ct. 278, 279, 69 L. Ed. 643, 61 Ct. Cl. 1019 (1925)* **[*22]** ([HN7] where there was a contract between only private entities, the subcontractor was unable to sue the United States pursuant to that contract); *National Leased Housing Assoc. v. United States, 105 F.3d 1423, 1435-37 (Fed. Cir. 1997)* (privity of contract with the United States is required in order to establish jurisdiction under the *Tucker Act*). As a non-party, the Government cannot be sued by Plaintiffs for breach of contract absent an indemnification agreement in the Prime Contract or some other provision demonstrating that the Government consented to an agency relationship with Plaintiffs. See e.g., *United States v. Johnson Controls, Inc., 713 F.2d 1541 (Fed. Cir. 1983)*.

[HN8] To demonstrate an agency relationship, a subcontractor must show that: (1) prime contractor was acting as a purchasing agent for the government; (2) the agency relationship between the government and the prime contractor was established by clear contractual consent; and (3) the prime contractor stated that the government would be directly liable to the subcontractors for the purchase price. See *id. at 1551*; *Globex Corp. v. United States, 54 Fed. Cl. 343, 348 (2002)*. **[*23]** "[A] contractor cannot bind the Government via provisions of a subcontract unless such authority has been granted by the Government." *Globex Corp., 54 Fed. Cl. at 350*. Courts look to the provisions of a prime contract to determine whether or not such consent exists. See *id. at 348*.

The former Fl contracts contained a separate indemnification provision which held the Government responsible for the actions of the fiscal intermediary. For Fl contracts, the federal funds given to its contractor were considered true pass-through funds. In other words, the contractor acted as a fiscal intermediary and just processed claims on behalf of the Government. The fiscal intermediary did not have any ownership interest in the funds transferred from federal coffers to the individual providers. At oral arguments in this case, Humana maintained that it was a "fiscal intermediary plus." Humana asserted that it merely processed the CHAMPUS/TRICARE claims for Regions 3 and 4, acting as a steward of the Government's funds. However, in addition to such fiscal intermediary duties, Humana admitted that it had to manage and cut costs, but at the same time argued that **[*24]** any additional duties did not alter its fiscal intermediary status.

Humana's "fiscal intermediary plus" argument is unavailing. In the present case, the Prime Contract is an MCS contract, and accordingly does not contain an indemnity provision like the former FI contracts. In creating MCS contracts, the DOD intentionally omitted an indemnity provision in an effort to alter the contractual relationship between the DOD and its healthcare contractors. The MCS contracts created an arrangement whereby the contractor (Humana) received control over a monthly allotment of governmental funds that the federal government electronically transferred to the contractor's bank account. The MCS contractor has ownership over the funds and can distribute those funds to network providers as it sees fit. The contractor cannot pay any claim beyond what federal law allows from the healthcare portion of the monthly allotment; however, the contractor is permitted to pay network providers beyond the Government's allowed amounts. If the contractor chooses to do so, then any overage is paid for out of the contractor's administrative portion of the allotment, which results in less profit for the contractor. **[*25]** Thus, the funds do not simply "pass-through" to the providers, as suggested by Humana. Similarly, Humana is not a fiscal intermediary. To the contrary, Humana is an MCS contractor with much greater responsibility and many more duties than a former FI contractor.

Furthermore, there is no provision in the Prime Contract whereby the DOD consents to an agency relationship with Humana. [13] To the contrary, there logically would not be such a provision if the Government restructured its healthcare contracts from FI to MCS contracts to alter the relationship between the DOD and its contractors. Plaintiffs cannot sue the Government for monetary damages based upon Humana's alleged breach of the network provider contracts. The Government is neither the real party in interest nor an indispensable party for Count I, and there is no basis for waiver of sovereign immunity by the Government. Humana is the real party in interest, thereby providing the Court with subject matter jurisdiction over Count I. Accordingly, Humana's motion to dismiss, or in the alternative, to transfer venue (see doc. 11) is DENIED.

13 Humana does not point to any such contractual provision in the Prime Contract.

[*26] ***B. Government's Motion to Dismiss***

In its Motion to Dismiss, the Government argues that Plaintiffs have no Article III standing to assert the declaratory judgment action in Count II. The Govern-

ment maintains that, as alleged, the complaint fails to demonstrate causation and redressability. Before addressing the Government's standing argument, it is important to explain the nature of the alleged injuries. In their response to the Government's motion to dismiss, Plaintiffs argue that their complaint asserts two types of damages, retrospective and prospective. The retrospective, or past, damages relate to Plaintiffs' receipt of less monies from Humana than that to which Plaintiffs claim a contractual entitlement. The prospective, or future, damages relate to Plaintiffs' claim that from the present time until the future expiration date of the network provider contracts Humana will continue to pay Plaintiffs less monies than that to which they are allegedly entitled. Second, Plaintiffs claim that the existence of the allegedly invalid DOD policy and regulation prevent Plaintiffs from negotiating new network provider contracts with Humana.

1. Standing

[*27] Although this case involves an agency policy and an agency regulation, the Government only challenges the existence of Article III standing under the United States Constitution. [HN9] "Standing is a threshold jurisdictional question which must be addressed prior to and independent of the merits of a party's claim." *Dillard v. Baldwin County Comm'rs, 225 F.3d 1271, 1275 (11th Cir. 2000)*. In order to satisfy the constitutional requirements of standing, a plaintiff must allege the following three things: (1) that he or she has suffered or will immediately suffer an injury; (2) that the injury is fairly traceable to the defendant's challenged actions; and (3) that a favorable court ruling is likely, as opposed to merely speculatively, to redress the plaintiff's injury. See *Bennett v. Spear, 520 U.S. 154, 167, 117 S. Ct. 1154, 1163, 137 L. Ed. 2d 281 (1997)*; *Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61, 112 S. Ct. 2130, 2136, 119 L. Ed. 2d 351 (1992)*; see also *Dillard, 225 F.3d at 1275*; ERWIN CHEMERINSKY, *Federal Jurisdiction,* § 2.3.1 (3d ed. 1999). Satisfaction of this three-part test is required where, as here, **[*28]** a plaintiff seeks to challenge agency action pursuant to the Administrative Procedure Act ("APA"), *5 U.S.C. § 701, et seq.* See *Moore v. Navy Public Works Center, 139 F. Supp. 2d 1349, 1354 (N.D. Fla. 2001)* (citations omitted). The Government's motion assumes that Plaintiffs have demonstrated an injury-in-fact; thus, the Government only challenges the existence of causation and redressability.

1. Causation

To satisfy the causation requirement, Plaintiffs must allege that the Government's issuance of the policy and regulation in question caused harm to Plaintiffs. See ERWIN CHEMERINSKY, *Federal Jurisdiction,* § 2.3.3 (3d ed. 1999).

> Importantly, [HN10] in evaluating Article III's causation (or "traceability") requirement, we are concerned with something less than the concept of "proximate cause." As [the Eleventh Circuit has] noted..., "no authority even remotely suggests that proximate causation applies to the doctrine of standing." Instead, even harms that flow indirectly from the action in question can be said to be "fairly traceable" to that action for standing purposes.

Focus on the Family v. Pinellas Suncoast Transit Authority, 344 F.3d 1263, 1273 (11th Cir. 2003) **[*29]** (citations omitted). [14]

> 14 "[To prove standing a plaintiff] must establish causation--a 'fairly...traceable' connection between the alleged injury in fact and the alleged conduct of the defendant." *Vermont Agency of Natural Res., 529 U.S. 765, 771, 146 L. Ed. 2d 836, 120 S. Ct. 1858, 1861 (2000)* (citations omitted).

The Government argues that Plaintiffs' injury was not caused by the Government's policies and regulations. The Government notes that Plaintiffs' complaint repeatedly alleges that their injury resulted from Humana's breaches of its network provider contracts. In addition, the complaint explicitly alleges that Plaintiffs' injury occurred independent of the policy and regulation in question. (Doc. 1, PP29, 31).

The Government is correct. The allegations in Plaintiffs complaint fail to meet Article III's causation requirement. Plaintiffs' injury involving alleged breach of contract damages of the receipt of less monies than that to which they allege entitlement, whether retrospective or **[*30]** prospective, are not "fairly traceable" to the Government's adoption of the policy and regulation. Those alleged damages are fairly traceable solely to the breach of contract claim. As to Plaintiffs' argument regarding prospective injury, Plaintiffs complaint does not adequately identify such an injury, even under a liberal construction of the complaint. As pled, the declaratory judgment action deals only with relief from the breach of the network provider contracts, already in place.

2. Redressability

[HN11] To meet the redressability requirement for standing, Plaintiffs' must allege that a favorable court decision is likely to remedy Plaintiffs' injury. See ER-

WIN CHEMERINSKY, *Federal Jurisdiction,* § 2.3.3 (3d ed. 1999). In other words, it must be likely, not merely speculative, that Plaintiffs' injury will be redressed by a favorable decision. See *Kelly v. Harris, 331 F.3d 817, 819-20 (11th Cir. 2003)* (citations omitted). The Government argues that Plaintiffs injury, *i.e.,* receiving less money than allegedly entitled from Humana, cannot be redressed with a declaratory judgment. The Government maintains that a favorable decision striking both the **[*31]** regulation and the policy as invalid will not result in Plaintiffs' receipt of the unpaid monies to which they claim a contractual entitlement.

The Government is again correct. Plaintiffs' explicit allegation that their injury occurred independent of the DOD policy and regulation in question is fatal to their claim. Furthermore, Plaintiffs complaint does not adequately identify a prospective injury. [15] Thus, there would be no injury to redress by a declaratory judgment. [16]

15 Assuming *arguendo* that the complaint asserted such a prospective injury, that injury would be extremely speculative, because there is nothing requiring either party to contract or to negotiate for a contract.

16 In addition, Count II presents no "actual controversy" as required by Article III. "Basically, [HN12] the question in each case is whether the facts alleged, under all of the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Maryland Casualty Co. v. Pacific Coal & Oil Co., 312 U.S. 270, 273, 61 S. Ct. 510, 512, 85 L. Ed. 826 (1941).* Whether the controversy is sufficiently immediate or real is a question of degree that must be determined on a case-by-case basis. *Golden v. Zwickler, 394 U.S. 103, 108, 89 S. Ct. 956, 959-60, 22 L. Ed. 2d 113 (1969); Simmonds Aerocessories, Ltd. v. Elastic Stop Nut Corp. of America, 257 F.2d 485, 489 (3rd Cir. 1958).* Based on the allegations in the Plaintiffs' complaint, there is no substantial controversy between Plaintiffs and the Government, no adverse legal interest between them, and no sufficient immediacy to warrant a declaratory judgment. Thus, as plead, the complaint fails to allege an "actual controversy" for Count II.

[*32] In sum, Plaintiffs' complaint fails on its face to demonstrate the causation and redressability requirements of Article III standing. Because the complaint fails to establish standing for Count II, the Government's motion to dismiss that count (see doc. 16) must be GRANTED. Count II, therefore, is DISMISSED without prejudice. Plaintiffs shall have fourteen (14) days from the date of this Order in which to file an amended complaint correcting the defects in Count II as outlined above. In the event Plaintiffs file an amended complaint, Defendants shall have ten (10) days thereafter to file a responsive pleading. See *FED. R. CIV. P. 15(a)* (2003). In the event Plaintiffs do not amend the complaint within the time period specified by the Court, Count II will be DISMISSED with prejudice. [17]

17 On January 9, 2004, the Court entered an Order staying the case and tolling the discovery period and all deadlines until Defendants' motions to dismiss were resolved. (Doc. 65). Because the current Order resolves Defendants' motions, the stay is hereby LIFTED. Because the stay is now lifted, the Clerk is directed to add sixty-seven (67) days to the discovery period in this case.

[*33] Accordingly, it is hereby ordered:

1. Defendant HUMANA MILITARY HEALTHCARE SERVICES, INC.'s Motion to Dismiss Plaintiffs' Complaint, or in the Alternative, to Transfer Pursuant to *28 U.S.C. § 1631* (see doc. 11) is DENIED.

2. Defendants TRICARE MANAGEMENT ACTIVITY and DONALD RUMSFELD's Motion to Dismiss, or Alternatively, to Stay Claim for Declaratory Judgment (see doc. 16) is GRANTED. Count II of the complaint is DISMISSED without prejudice. Plaintiffs shall have fourteen (14) days from the date of this Order in which to file an amended complaint correcting the defects in Count II as outlined above. In the event Plaintiffs file an amended complaint, Defendants shall have ten (10) days thereafter to file a responsive pleading. See *FED. R. CIV. P. 15(a)* (2003). In the event Plaintiffs do not amend the complaint within the time period specified by the Court, Count II will be DISMISSED with prejudice.

3. The stay in this case (see doc. 65) is LIFTED. Therefore, the Clerk is directed to add sixty-seven (67) days to the discovery period in this case.

ORDERED on this 16th day of March 2004.

M. **[*34]** CASEY RODGERS

United States District Judge

EXHIBIT "D"

Uniform Bill Form (UB-92), page 1

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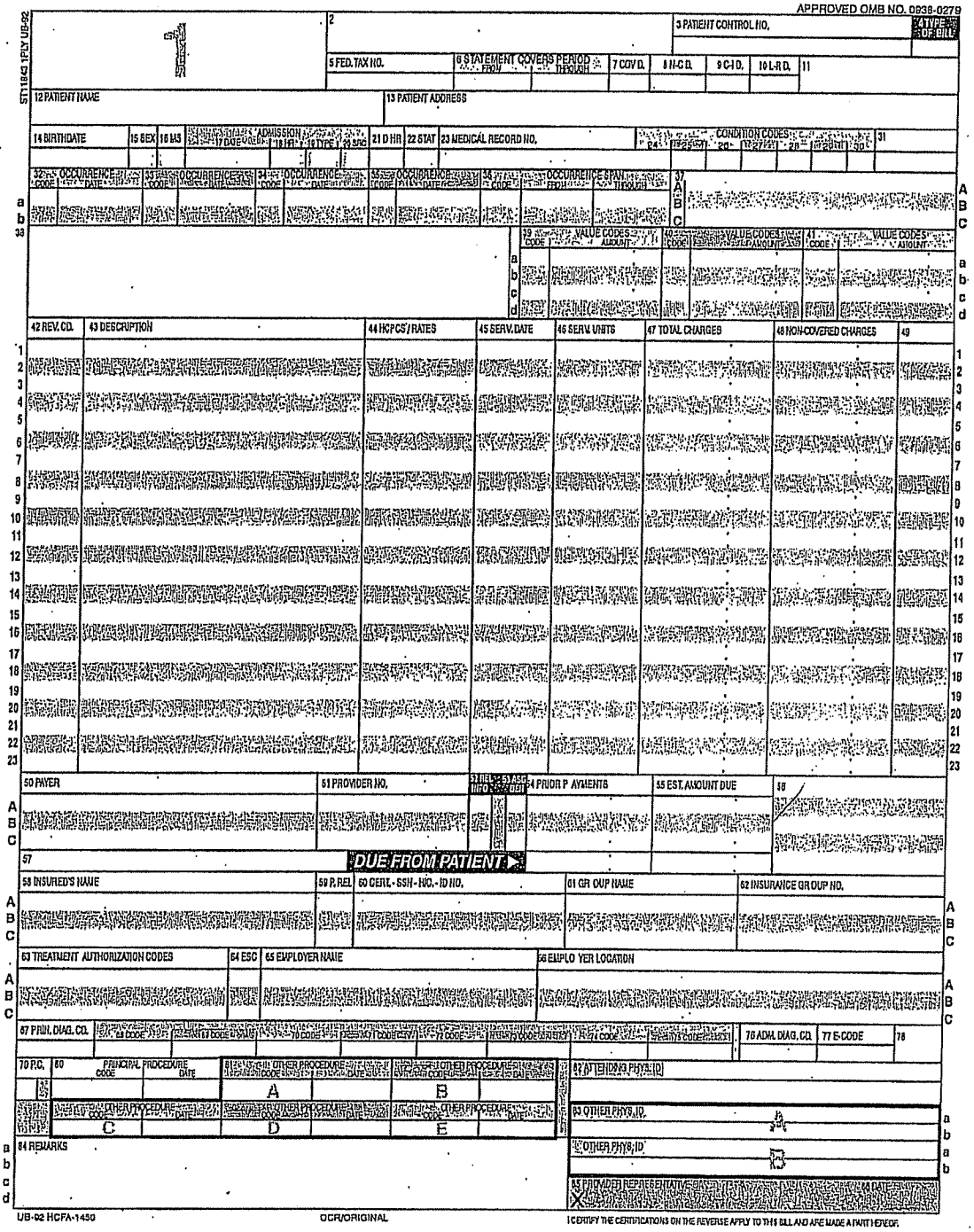

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LAKEWOOD HEALTH SYSTEM AND NORTHWEST MEDICAL CENTER, *for themselves and on behalf of all other similarly situated class members,*	Civil Action No. 07-69 (GMS)
Plaintiffs,	JURY TRIAL DEMANDED
v.	CLASS ACTION
TRIWEST HEALTHCARE ALLIANCE CORP.,	
Defendant.	

CERTIFICATE OF SERVICE

I, Aimee Czachorowski, hereby certify that on October 12, 2007, I caused 2 copies of the Memorandum of Law of Plaintiffs in Response to the Statement of Interest of the United States to be served upon the following counsel of record via e-filing and hand delivery:

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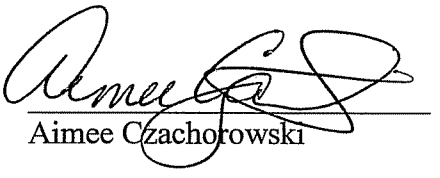

Aimee Czachorowski